GeneXpert Software

4.4 version

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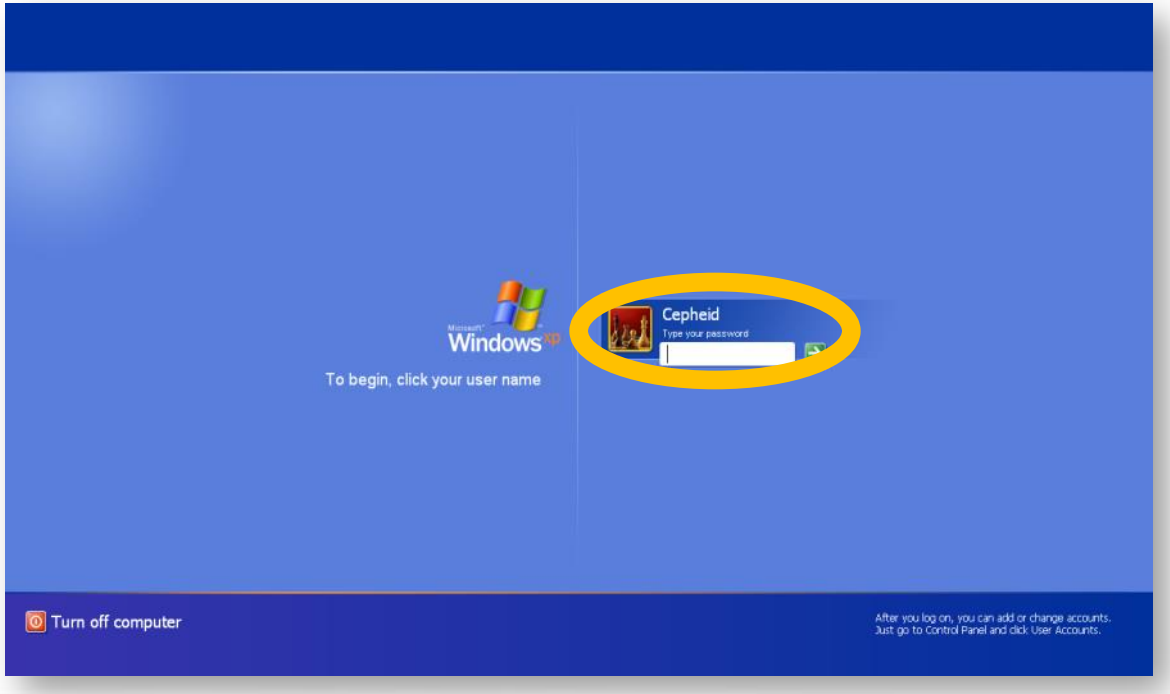
Start the Windows Operating System (Windows XP - 1st generation)

1. Switch on the GeneXpert®: a small blue light will appear at the front panel of the system
2. Switch on the Computer
3. Open the Windows XP session: Username: **Cepheid** Password: **cphd**


Windows XP
To begin, click your user name
Cepheid
Type your password
Turn off computer
After you log on, you can add or change accounts.
Just go to Control Panel and click User Accounts.

Start the Windows Operating System (Windows 7 - 2nd generation)

1. Switch on the GeneXpert®: a small blue light will appear at the front panel of the system
2. Switch on the Computer
3. Open the Windows 7 session:
   Select the Username **Cepheid** and Type the password: **cphd**

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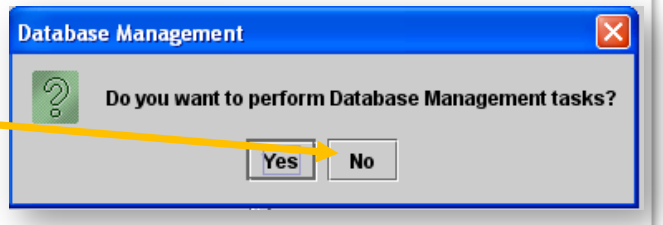
Prepare your system for the routine use

4 Please wait a little until the GeneXpert DX software starts automatically

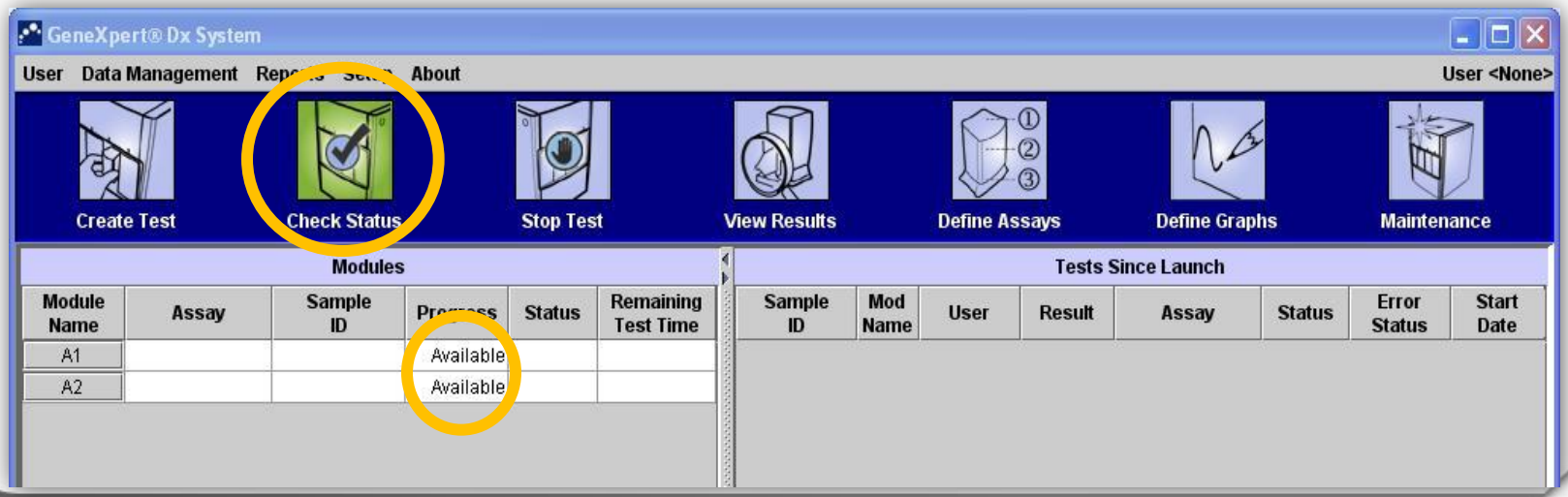
When you will start the program, the question *"**Do you want to perform database management task** " will appear:*

Click on **NO** when you begin your working day



5 In the Check Status screen, verify that all modules are available

(If modules are not available, please refer to chapter 11 of the Operator Manual and contact Cepheid technical support)



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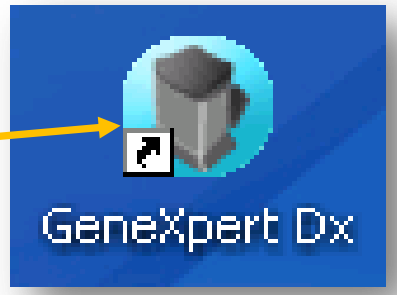
Prepare your system for the routine use

In case the software was closed (computer still opened), to reopen it, double - click on the «GeneXpert DX» on the desktop and follow steps 4 and 5 page 3)



Create an Administrator Account ("Admin")

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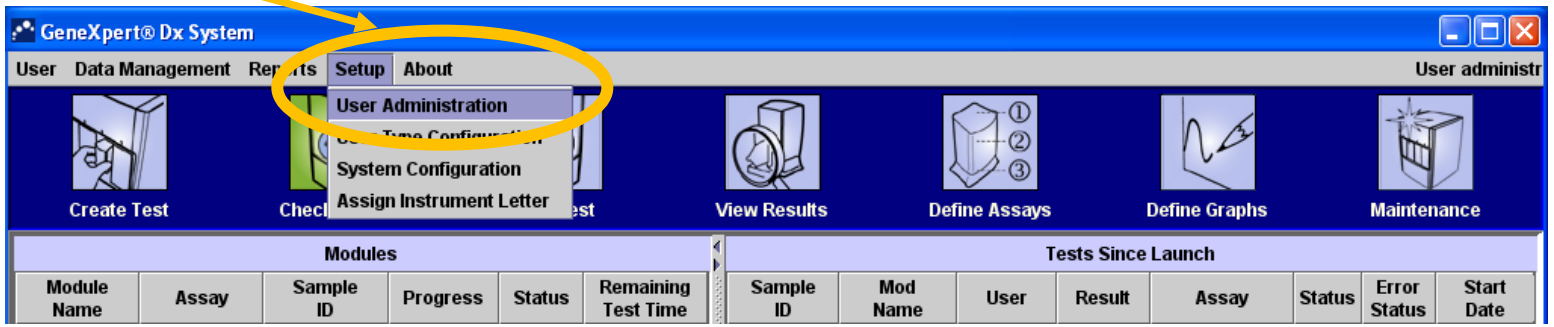
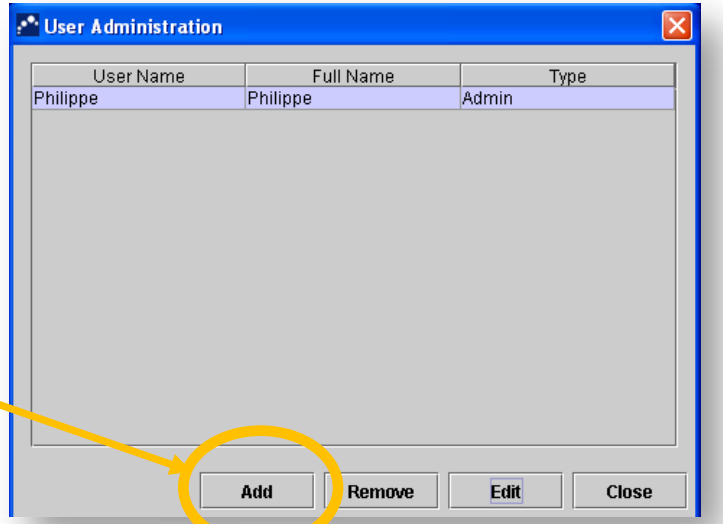
Create an Administrator Account ("Admin")

1 Select Setup → User administration



2 Click on ("Add")



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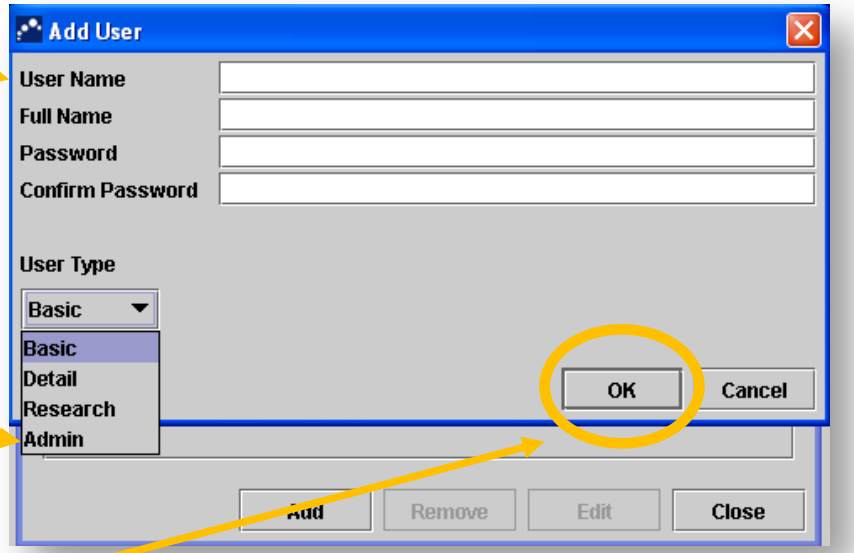
Create an Administrator Access (“Admin”)

1 Enter your Username and Password

2 Choose the User type: “Admin”

3 Click on “OK”



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Create a Basic Account

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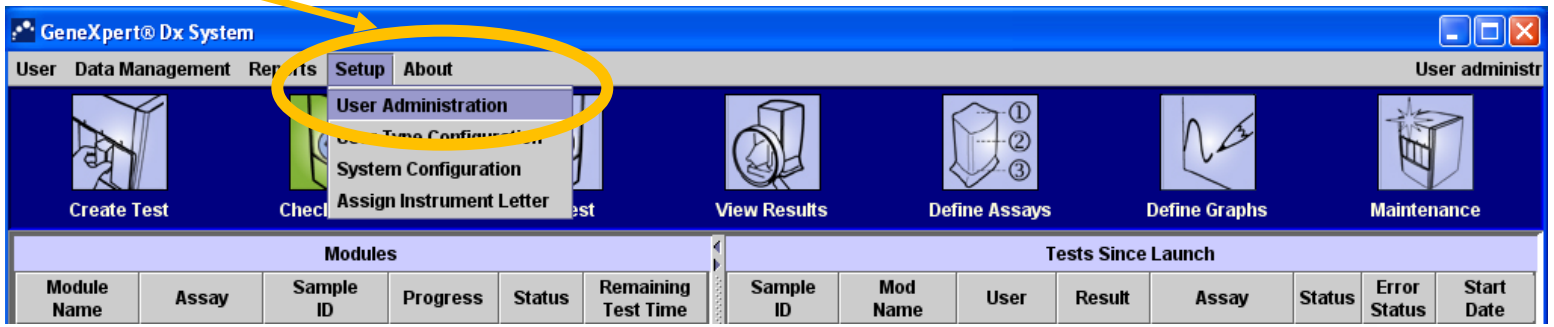
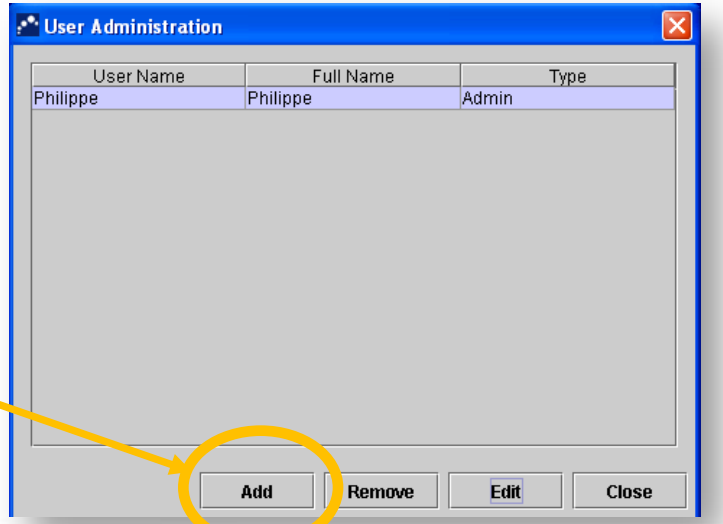
Create a Basic Account

Define the persons in the lab that will have limited access to the software. Can be more than one Basic account per system.

1 Select Setup → User administration



2 Click on ("Add")



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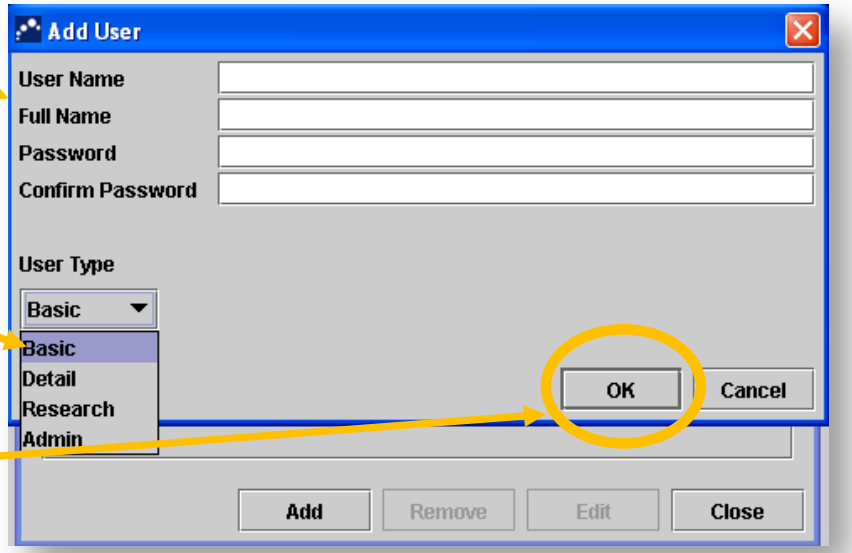
Create an Basic Account (“Basic”)

1. Enter your Username and Password
2. Choose the User type: “Basic”
3. Click on “OK”



Remarks: The basic access will only be able to see the results without the graphics.

Routine use

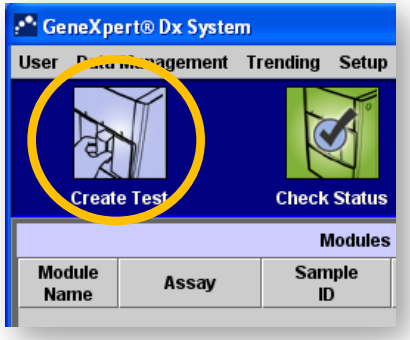
Create a test

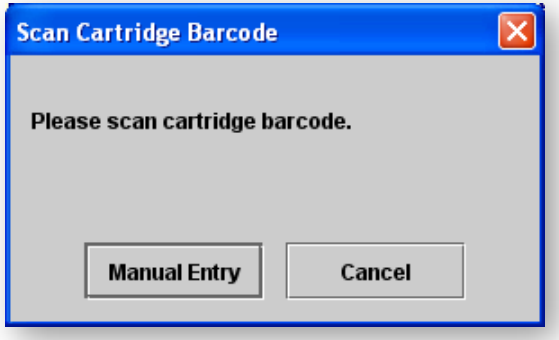
Create a test

1 Click on CREATE TEST

2 A dialogue box will appear: Please scan cartridge barcode

3 Press the yellow button of the barcode scanner and scan the cartridge





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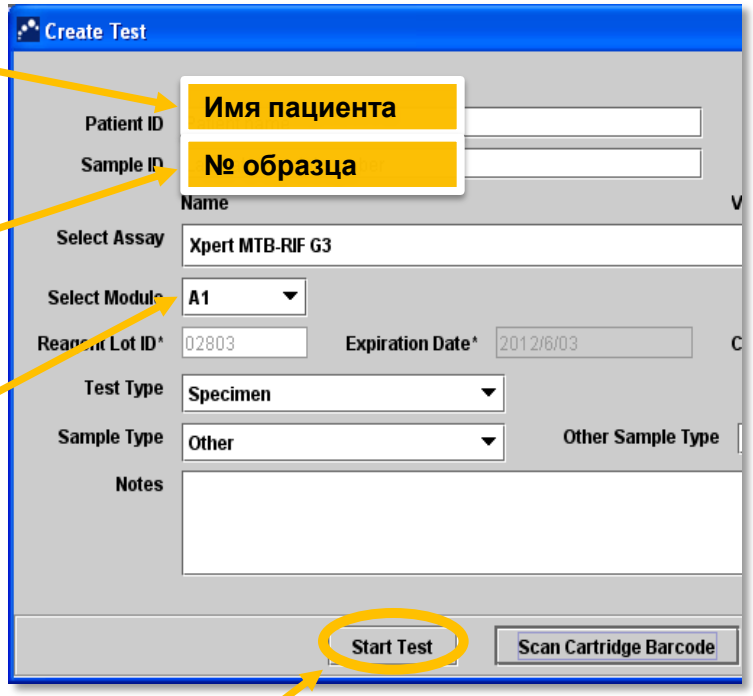
Create a test

Once done, the below screen will appear

4 Fill in the Patient ID if available

5 Fill in the Sample ID

6 The module will be automatically selected **DO NOT CHANGE IT**



7 Click on Start Test

8 A green light will blink from a given module: Open the door and place the cartridge

9 Fully close the module door, the test starts immediately
Wait 2 hour to see your result

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Routine use

Manual Entry of the cartridge barcode

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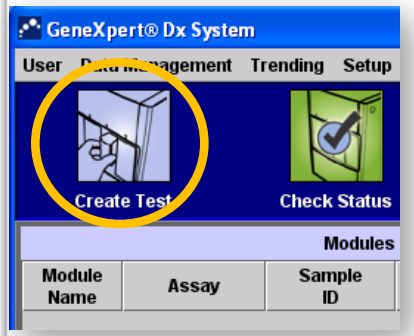
Manual Entry of the cartridge barcode

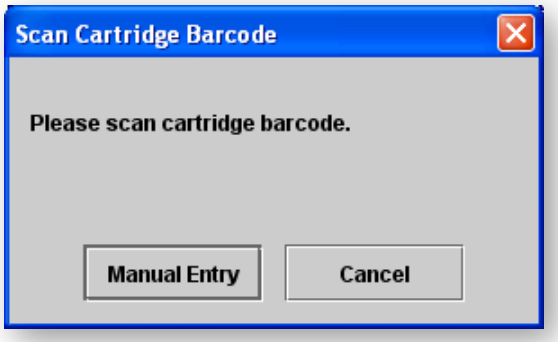
If the barcode scanner is not working at that moment you can enter the cartridge barcode manually

1 Click on «Create Test»

2 A dialogue box will appear:
Please scan cartridge barcode:
Click on MANUAL ENTRY

3 Type manually the 2 line numbers of the cartridges – see the picture





!!! In case of barcode reader failure while using a new lot, this action cannot be completed. Please contact Cepheid technical support to collect the Lot Specific Parameter.

4 Wait 2 hour to see your result

Enter the number without space!!

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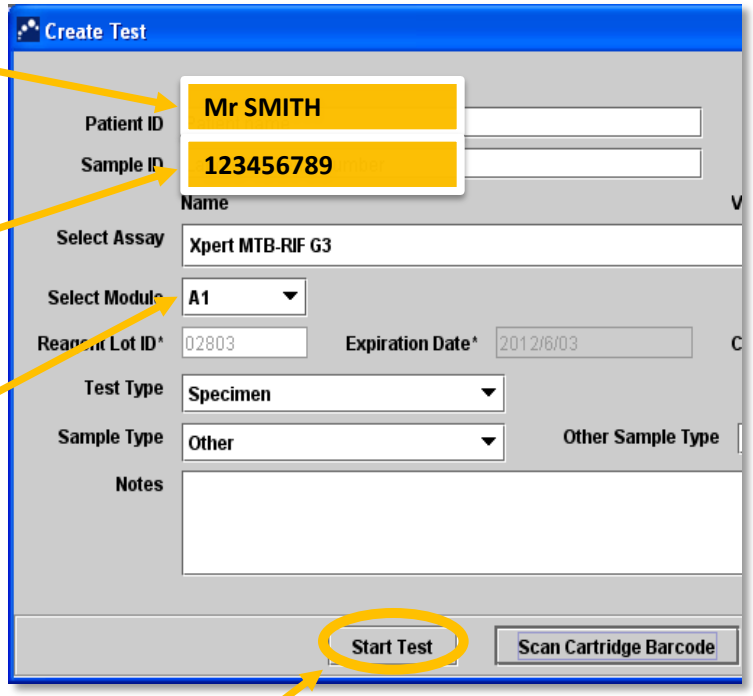
Create a test

Once done, the below screen will appear

4 Fill in the Patient ID if available

5 Fill in the Sample ID

6 The module will be automatically selected
DO NOT CHANGE IT



7 **Click on Start Test**

8 A green light will blink from a given module: Open the door and place the cartridge

9 Fully close the module door, the test starts immediately
Wait 2 hours to see your result

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How to stop a test and why

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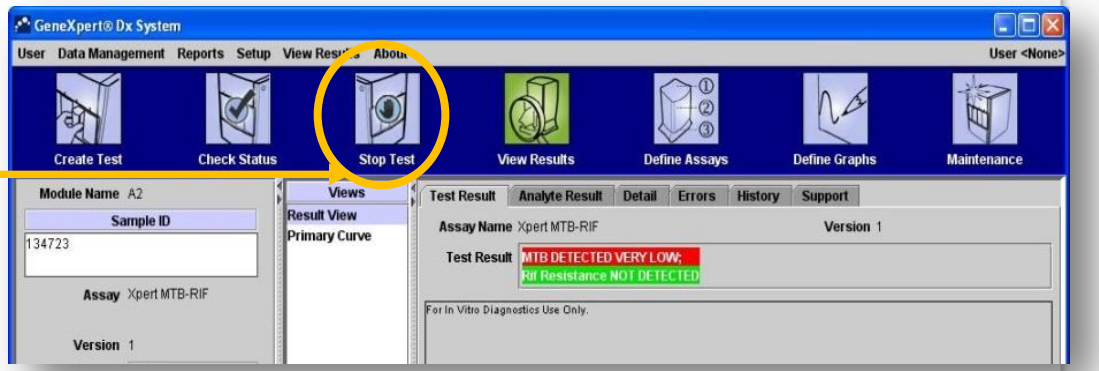
How to stop a test and why

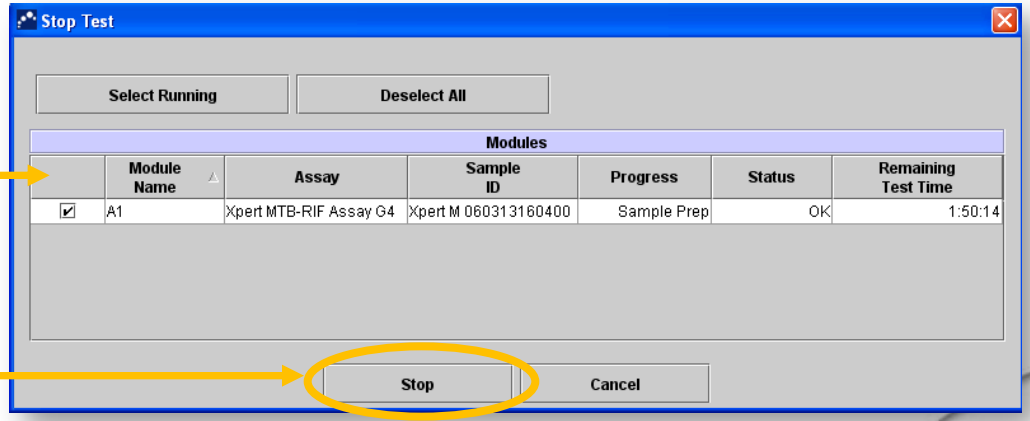
In case your cartridge(s) was(were) not properly prepared, you might have to stop the test to avoid waist of time

1 Click “Stop Test”



2 Select the module(s) that need to be stopped, by marking the tickbox

3 After selecting click “Stop”



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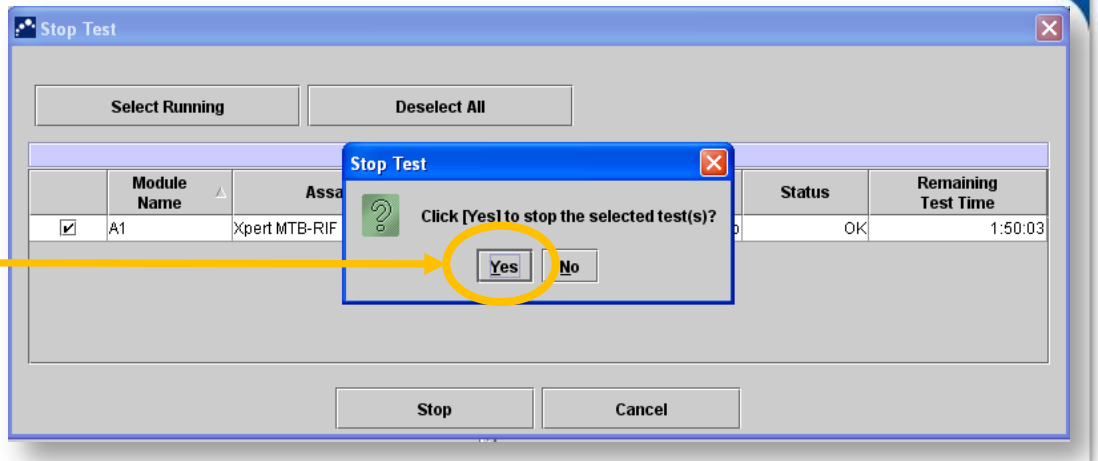
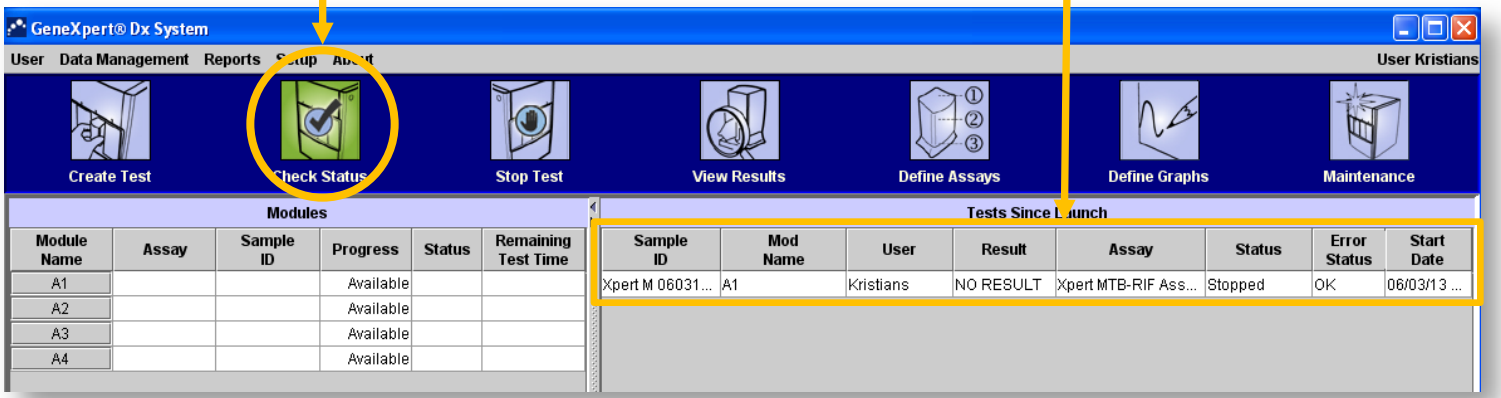
How to stop a test and why

4 Confirm your choice by clicking “Yes”



5 You will see the stopped test’s details in Check Status section



VIEW RESULTS

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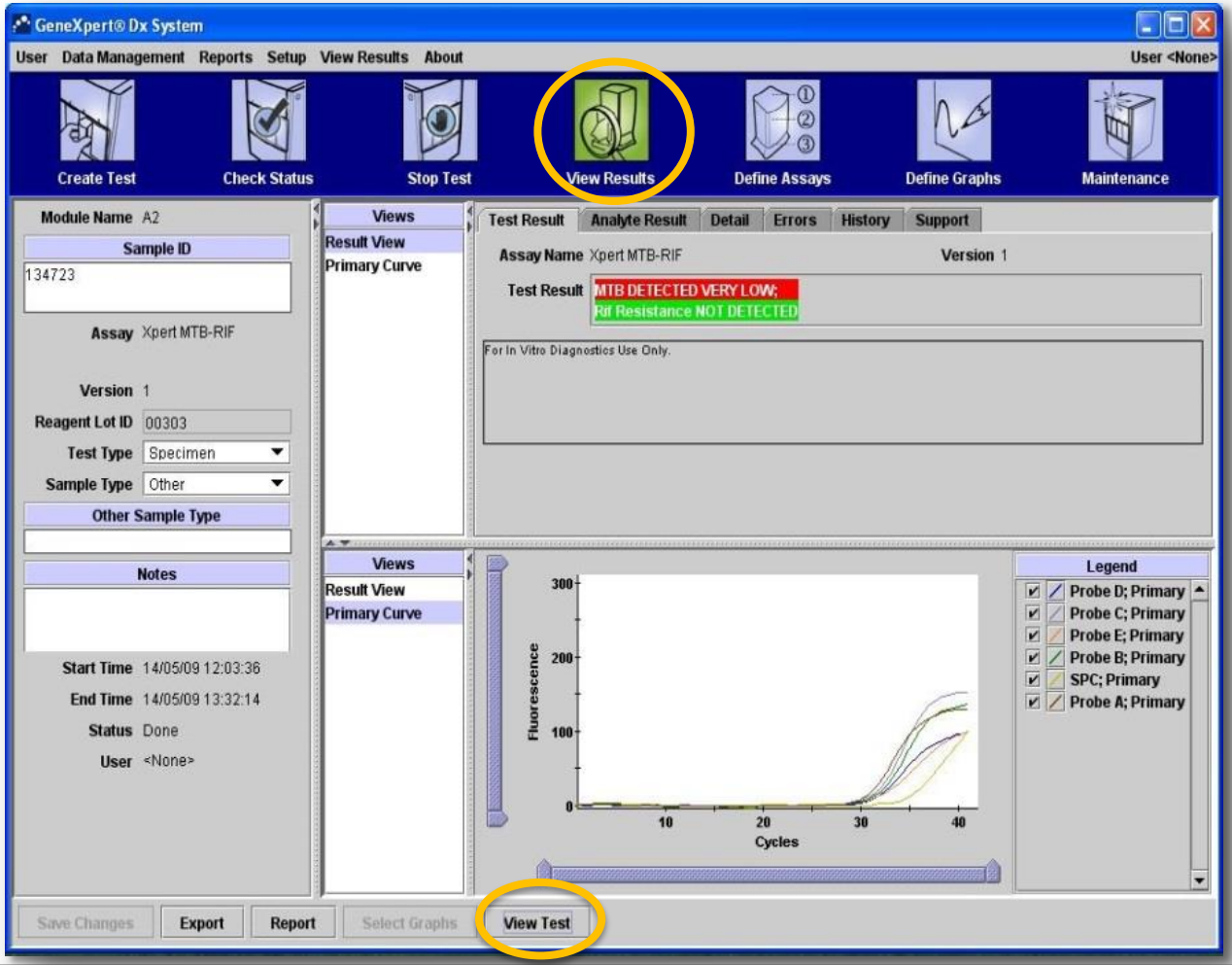
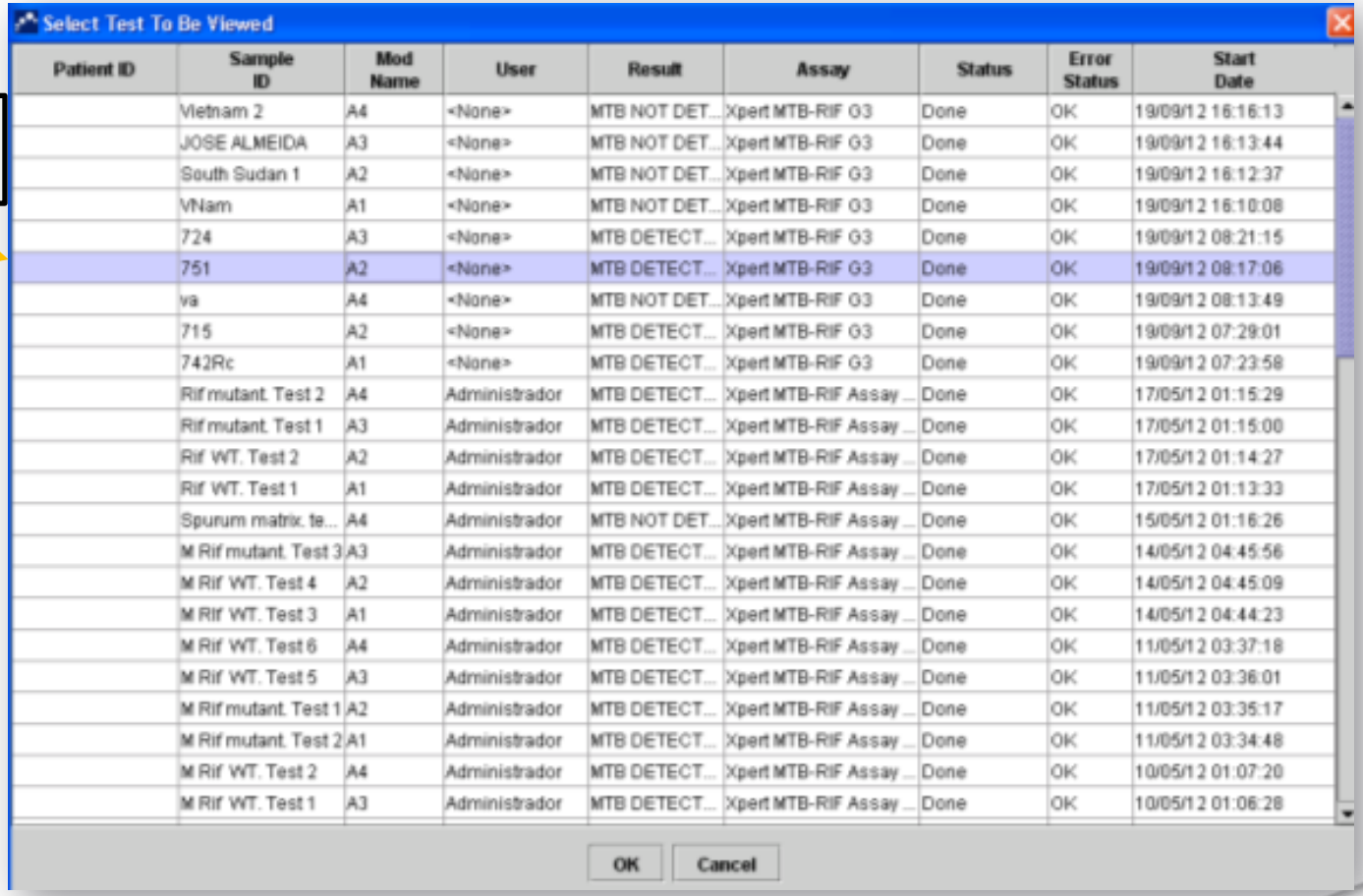
View results

Click on “VIEW RESULTS”
To visualize one particular result, click on «**VIEW TEST»**



View results

Double click on the test you want to see


Select Test To Be Viewed
Patient ID
Sample ID
Mod Name
User
Result
Assay
Status
Error Status
Start Date
Vietnam 2 A4 <None> MTB NOT DET... Xpert MTB-RIF G3 Done OK 19/09/12 16:16:13
JOSE ALMEIDA A3 <None> MTB NOT DET... Xpert MTB-RIF G3 Done OK 19/09/12 16:13:44
South Sudan 1 A2 <None> MTB NOT DET... Xpert MTB-RIF G3 Done OK 19/09/12 16:12:37
VNam A1 <None> MTB NOT DET... Xpert MTB-RIF G3 Done OK 19/09/12 16:10:08
724 A3 <None> MTB DETECT... Xpert MTB-RIF G3 Done OK 19/09/12 08:21:15
751 A2 <None> MTB DETECT... Xpert MTB-RIF G3 Done OK 19/09/12 08:17:06
va A4 <None> MTB NOT DET... Xpert MTB-RIF G3 Done OK 19/09/12 08:13:49
715 A2 <None> MTB DETECT... Xpert MTB-RIF G3 Done OK 19/09/12 07:29:01
742Rc A1 <None> MTB DETECT... Xpert MTB-RIF G3 Done OK 19/09/12 07:23:58
Rif mutant. Test 2 A4 Administrador MTB DETECT... Xpert MTB-RIF Assay ... Done OK 17/05/12 01:15:29
Rif mutant. Test 1 A3 Administrador MTB DETECT... Xpert MTB-RIF Assay ... Done OK 17/05/12 01:15:00
Rif WT. Test 2 A2 Administrador MTB DETECT... Xpert MTB-RIF Assay ... Done OK 17/05/12 01:14:27
Rif WT. Test 1 A1 Administrador MTB DETECT... Xpert MTB-RIF Assay ... Done OK 17/05/12 01:13:33
Spurum matrix. te... A4 Administrador MTB NOT DET... Xpert MTB-RIF Assay ... Done OK 15/05/12 01:16:26
M Rif mutant. Test 3 A3 Administrador MTB DETECT... Xpert MTB-RIF Assay ... Done OK 14/05/12 04:45:56
M Rif WT. Test 4 A2 Administrador MTB DETECT... Xpert MTB-RIF Assay ... Done OK 14/05/12 04:45:09
M Rif WT. Test 3 A1 Administrador MTB DETECT... Xpert MTB-RIF Assay ... Done OK 14/05/12 04:44:23
M Rif WT. Test 6 A4 Administrador MTB DETECT... Xpert MTB-RIF Assay ... Done OK 11/05/12 03:37:18
M Rif WT. Test 5 A3 Administrador MTB DETECT... Xpert MTB-RIF Assay ... Done OK 11/05/12 03:36:01
M Rif mutant. Test 1 A2 Administrador MTB DETECT... Xpert MTB-RIF Assay ... Done OK 11/05/12 03:35:17
M Rif mutant. Test 2 A1 Administrador MTB DETECT... Xpert MTB-RIF Assay ... Done OK 11/05/12 03:34:48
M Rif WT. Test 2 A4 Administrador MTB DETECT... Xpert MTB-RIF Assay ... Done OK 10/05/12 01:07:20
M Rif WT. Test 1 A3 Administrador MTB DETECT... Xpert MTB-RIF Assay ... Done OK 10/05/12 01:06:28
OK
Cancel

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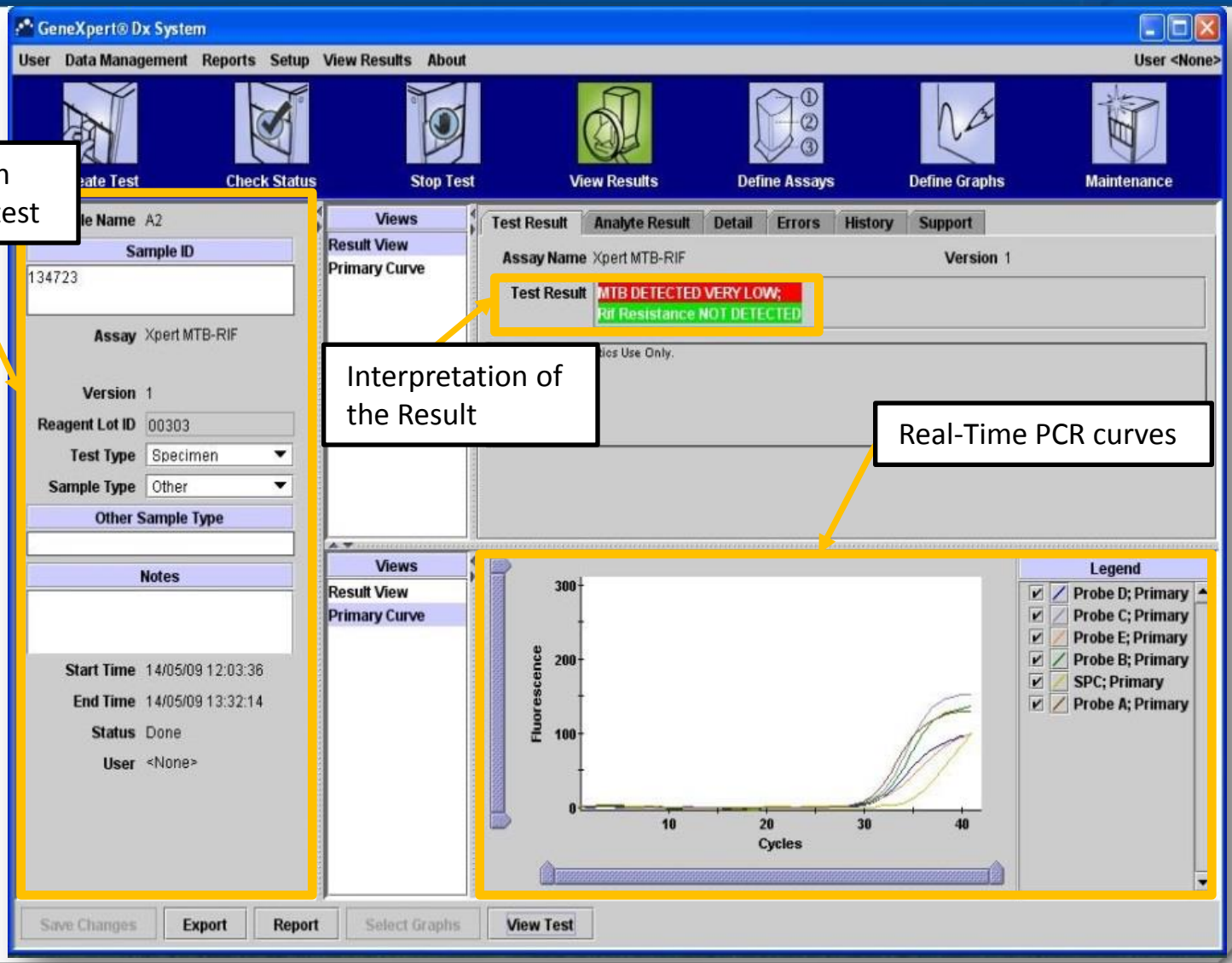
View results



How to edit test related information

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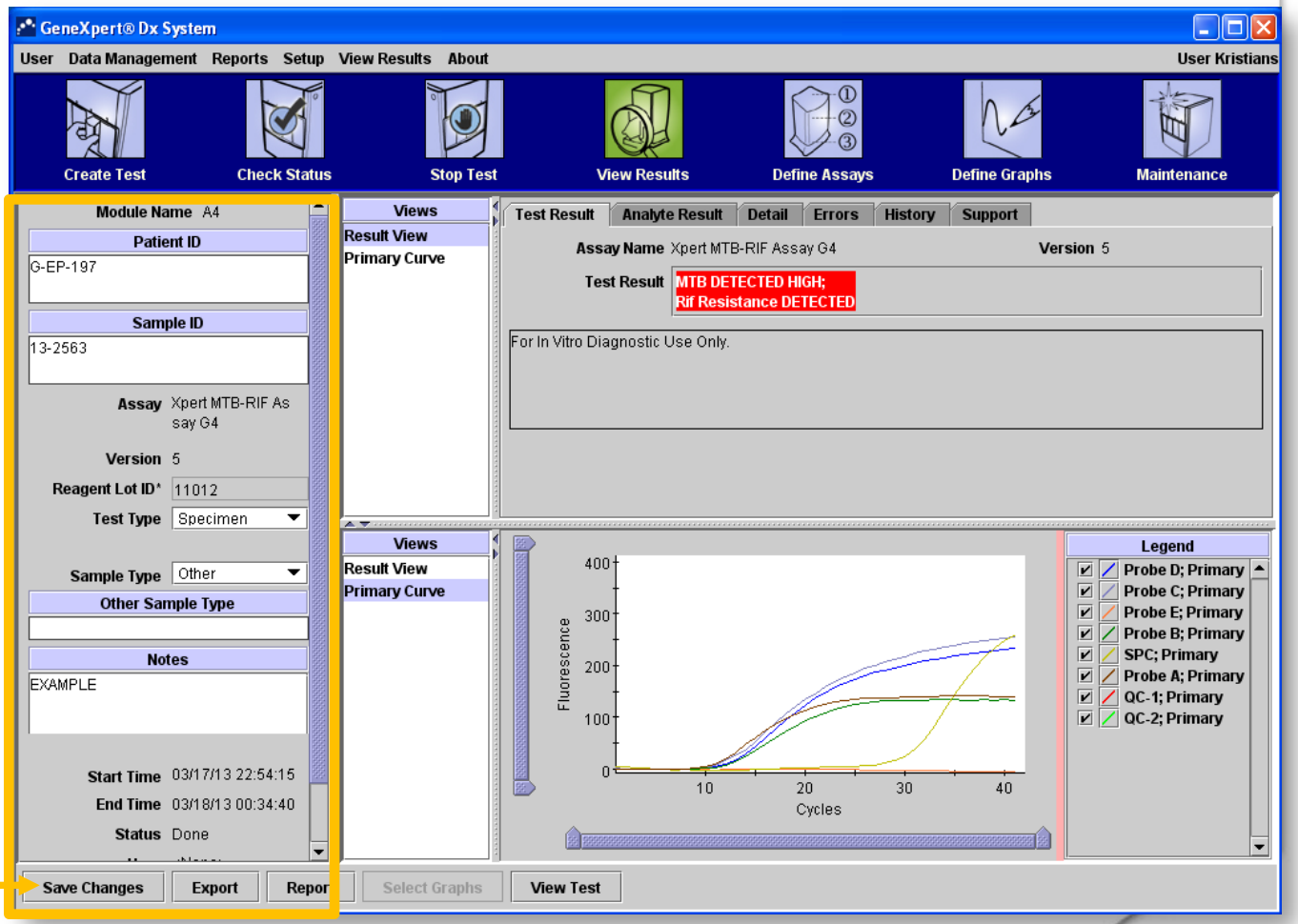
Edit test related info sample id

If necessary you can edit the test related information and notes after the is finished of while it's running

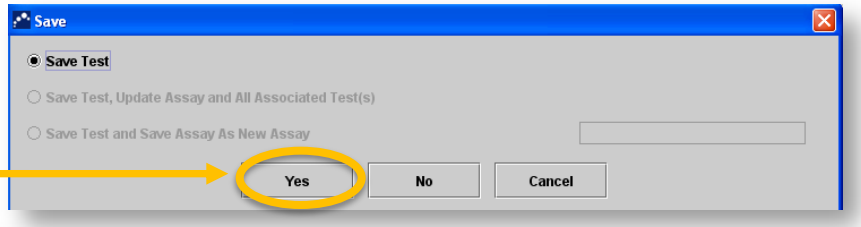
1 All the white fields in this section are editable

2 After editing click "Save Changes"

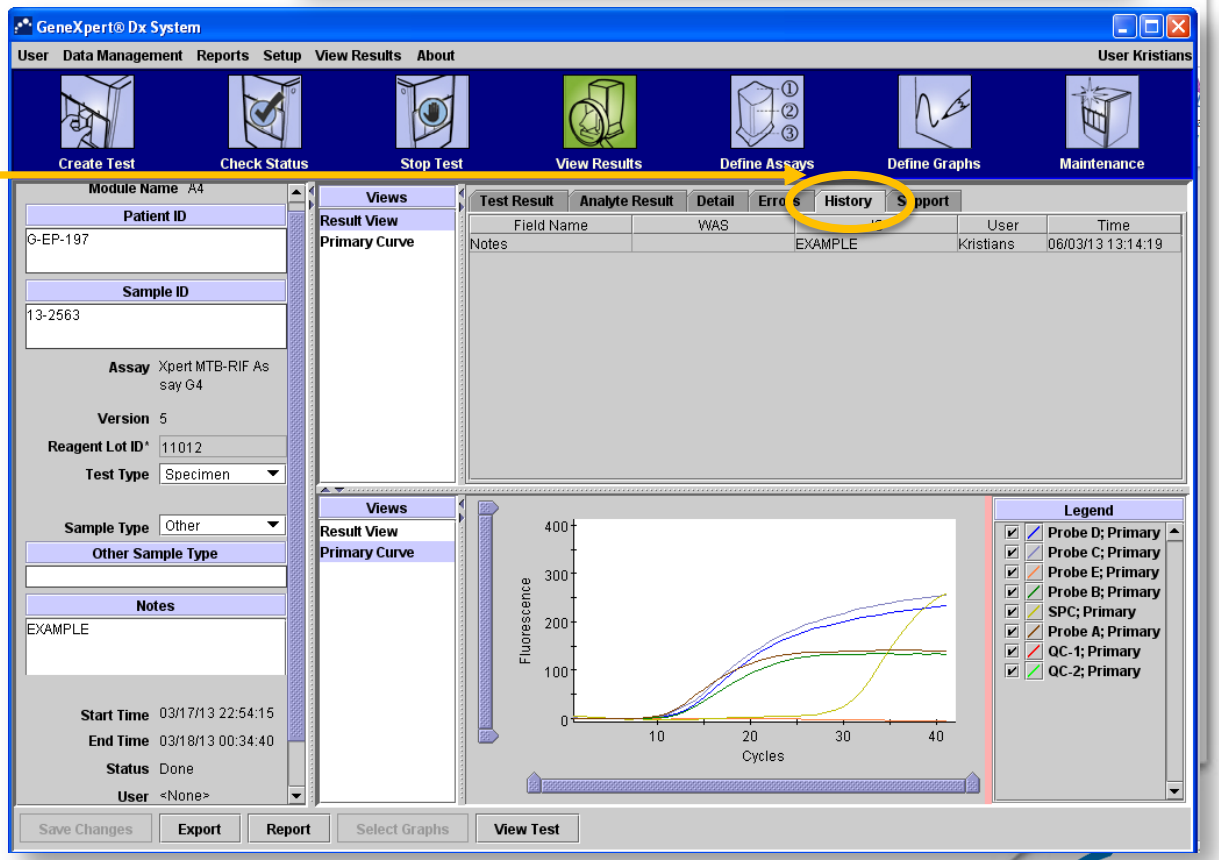


Edit test related info sample id

3 Click “Yes” to confirm the changes



4 The history of the changed information is saved under the tab “History”



Generate a result report in pdf

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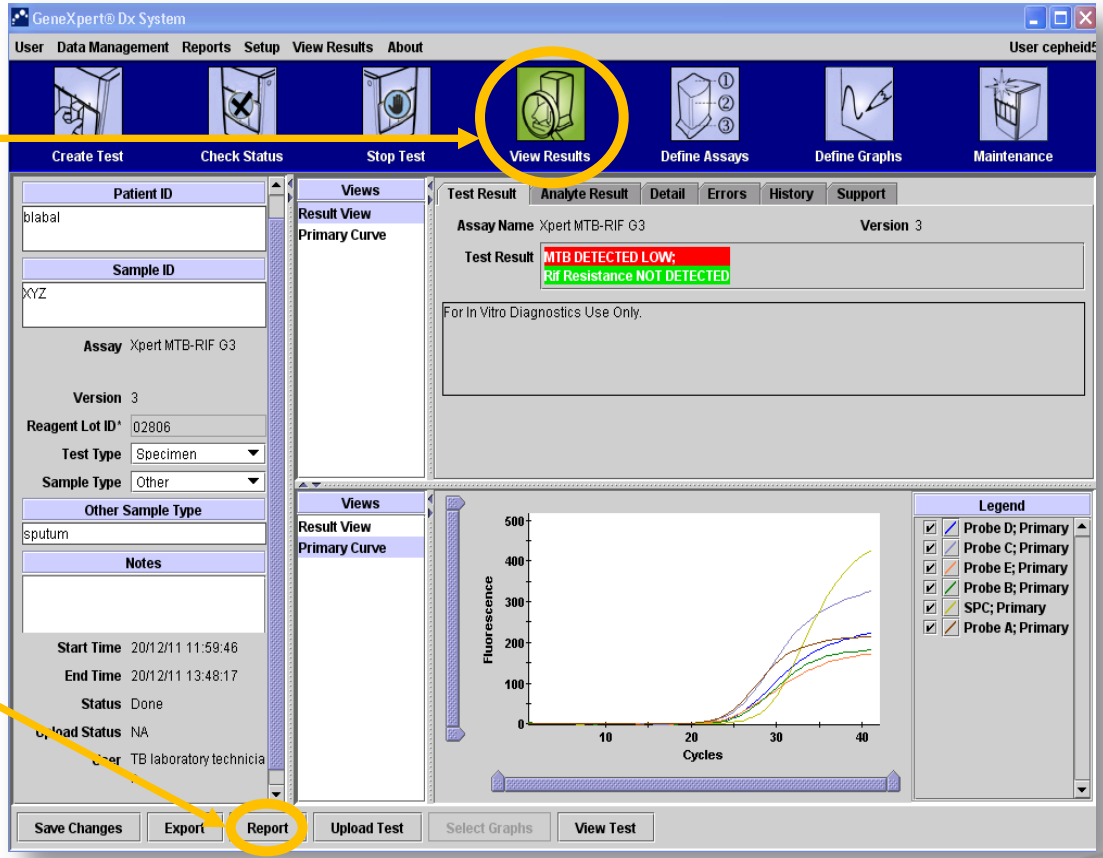
Generate a result report in pdf format

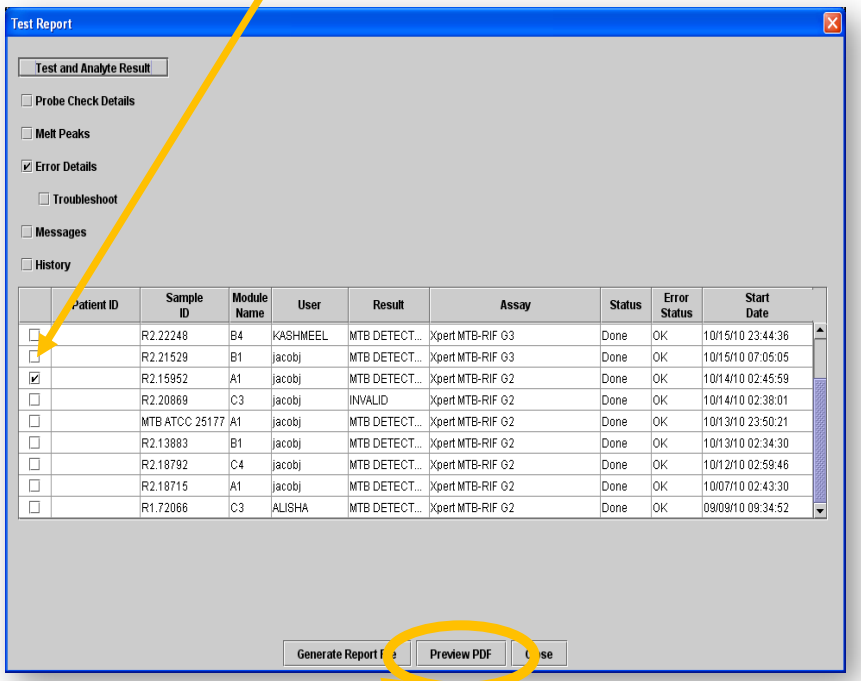
1 Click on “VIEW RESULT”

2 Click on "REPORT”

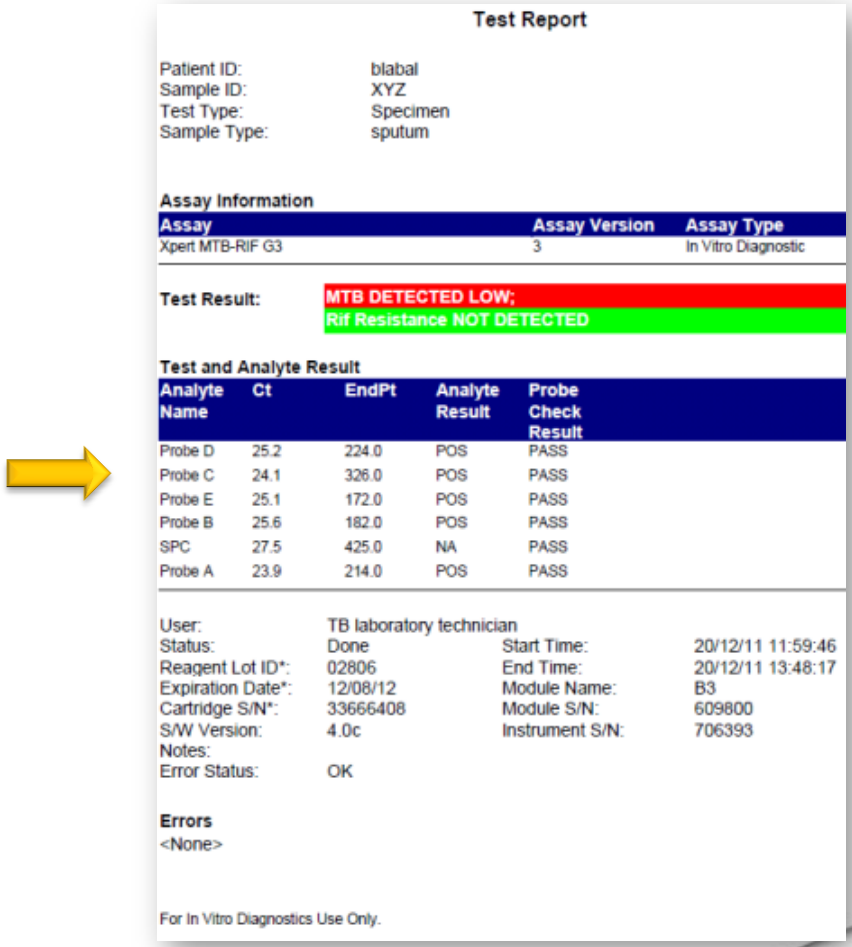


How to generate a pdf report

3 Select the result you may want to visualize in pdf


Test Report
Test and Analyte Result
Probe Check Details
Melt Peaks
Error Details
Troubleshoot
Messages
History
Patient ID
Sample ID
Module Name
User
Result
Assay
Status
Error Status
Start Date
R2.22248 B4 KASHMEEL MTB DETECT... Xpert MTB-RIF G3 Done OK 10/15/10 23:44:36
R2.21529 B1 jacobj MTB DETECT... Xpert MTB-RIF G3 Done OK 10/15/10 07:05:05
R2.15952 A1 jacobj MTB DETECT... Xpert MTB-RIF G2 Done OK 10/14/10 02:45:59
R2.20869 C3 jacobj INVALID Xpert MTB-RIF G2 Done OK 10/14/10 02:38:01
MTB ATCC 25177 A1 jacobj MTB DETECT... Xpert MTB-RIF G2 Done OK 10/13/10 23:50:21
R2.13883 B1 jacobj MTB DETECT... Xpert MTB-RIF G2 Done OK 10/13/10 02:34:30
R2.18792 C4 jacobj MTB DETECT... Xpert MTB-RIF G2 Done OK 10/12/10 02:59:46
R2.18715 A1 jacobj MTB DETECT... Xpert MTB-RIF G2 Done OK 10/07/10 02:43:30
R1.72066 C3 ALISHA MTB DETECT... Xpert MTB-RIF G2 Done OK 09/09/10 09:34:52
Preview PDF

4 Click on “Preview pdf” for immediate vizualisation



Test Report

Patient ID: blabal
Sample ID: XYZ
Test Type: Specimen
Sample Type: sputum

Assay Information

Assay	Assay Version	Assay Type
Xpert MTB-RIF G3	3	In Vitro Diagnostic

Test Result: MTB DETECTED LOW; Rif Resistance NOT DETECTED

Test and Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
Probe D	25.2	224.0	POS	PASS
Probe C	24.1	326.0	POS	PASS
Probe E	25.1	172.0	POS	PASS
Probe B	25.6	182.0	POS	PASS
SPC	27.5	425.0	NA	PASS
Probe A	23.9	214.0	POS	PASS

User: TB laboratory technician
Status: Done
Reagent Lot ID*: 02806
Expiration Date*: 12/08/12
Cartridge S/N*: 33666408
S/W Version: 4.0c
Notes:
Error Status: OK

Start Time: 20/12/11 11:59:46
End Time: 20/12/11 13:48:17
Module Name: B3
Module S/N: 609800
Instrument S/N: 706393

Errors
<None>

For In Vitro Diagnostics Use Only.

How to generate specimen and patient reports in pdf

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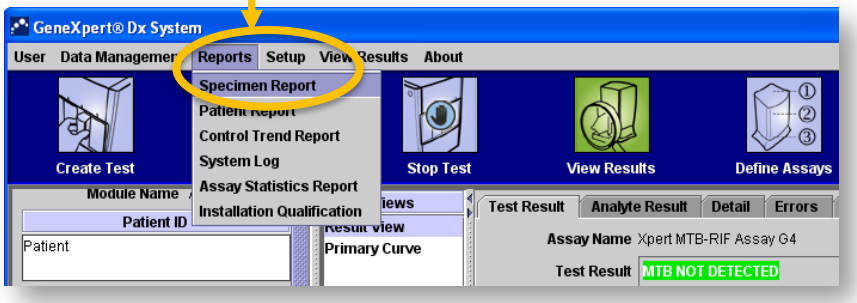
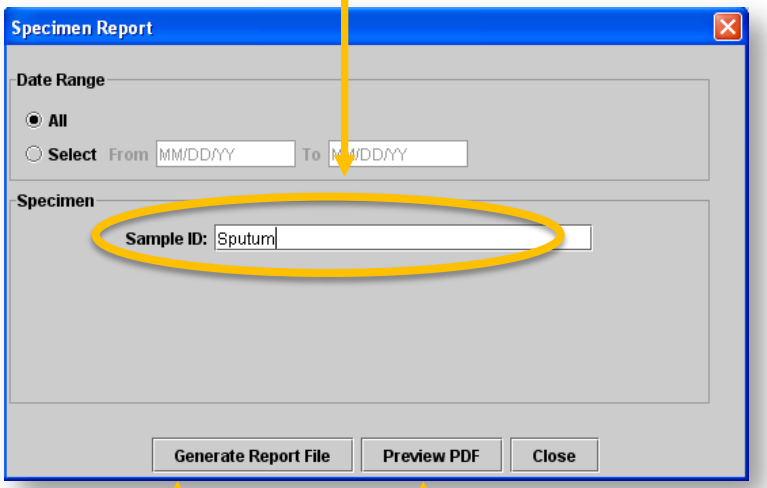
How to generate specimen and patient reports in pdf

Specimen Report

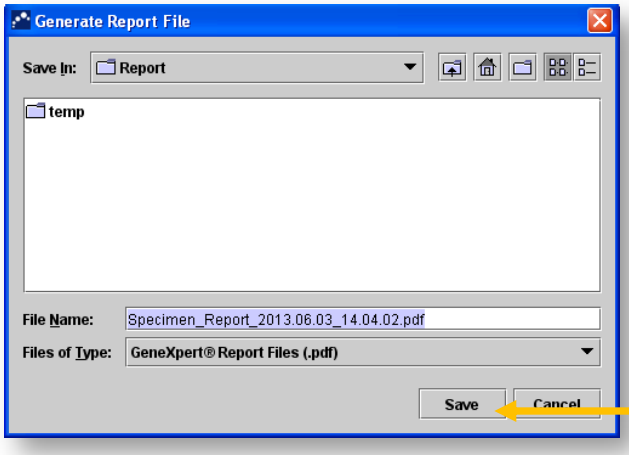
1 Click Reports -> Specimen Report



2 Fill in the Sample ID



3 "Preview PDF" will open the pdf file



3a "Generate Report File" will save the report in GeneXpert Folder -> Report

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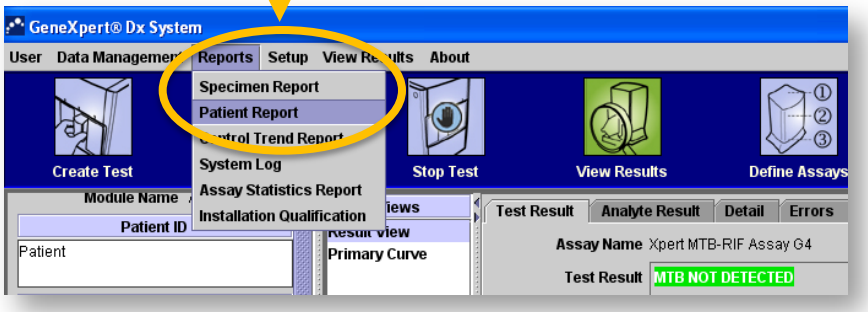
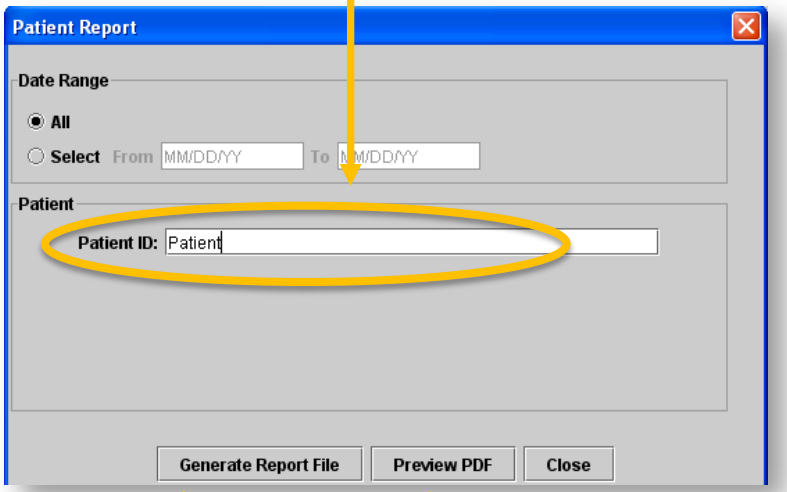
How to generate specimen and patient reports in pdf

Patient Report

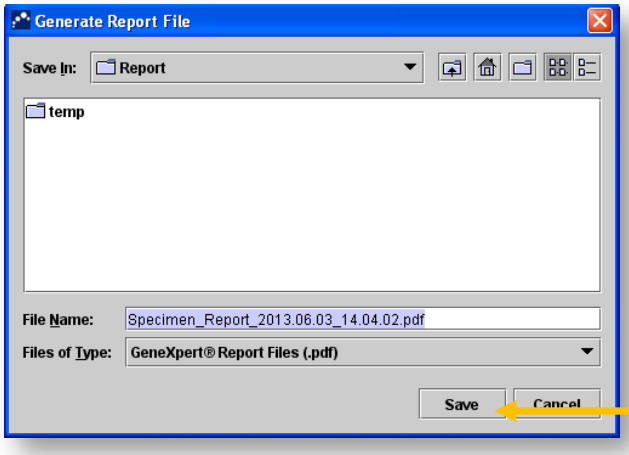
1 Click Reports -> Patient Report



2 Fill in the Patient ID



3 "Preview PDF" will open the pdf file



3a "Generate Report File" will save the report in GeneXpert Folder -> Report

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How to print automatically test report

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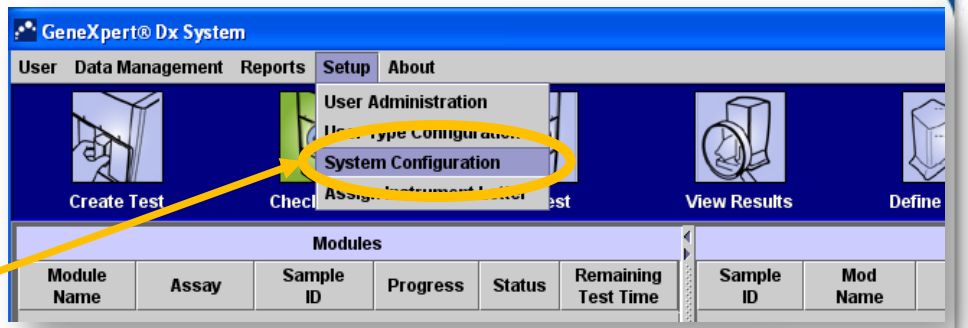
How to print automatically test report

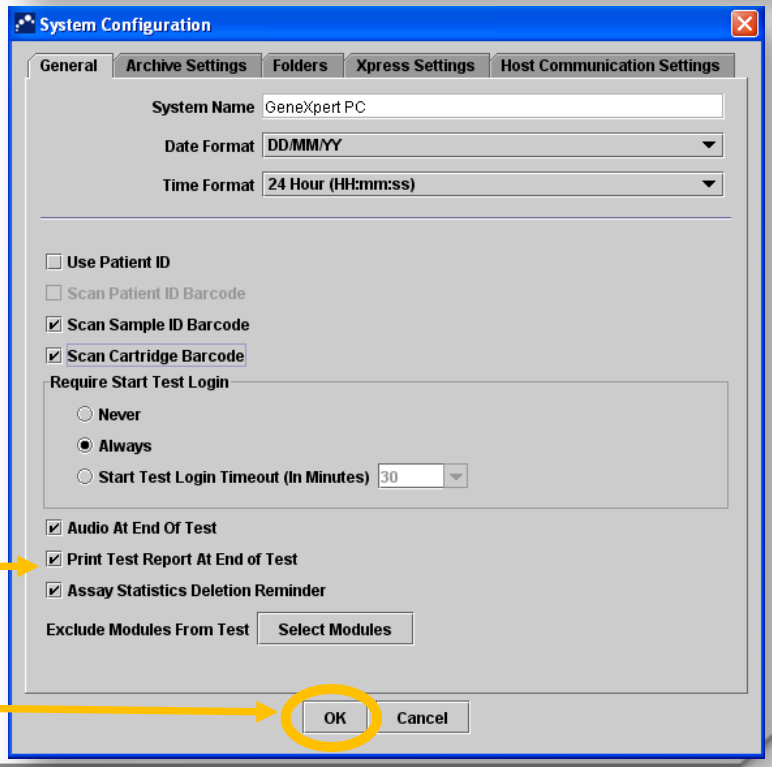
- Connect and install your printer
- You can print every report once test is finished

1 Click on ''Setup'', then "System configuration"



2 Select the appropriate option ''Print Test Report At End of Test''

3 Click ''OK''



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Data management tasks

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Difference between Archive/Backup

The **Archive** contains only the raw results

- *the technical Support will request you that file in case of complaint*
- *can only be retrieved with GeneXpert DX software*
- *Save the archive every week on a CD or RW-CD*
- *extension is .gxx*

The **Backup** contains all information about the system (Log files, errors, raw results, definition of assays)

- *can be used to restore the data on the GeneXpert DX software in case of computer failure*
- *backup all your data every month on a CD or RW-CD*
- *extension is .zip*

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How to archive results

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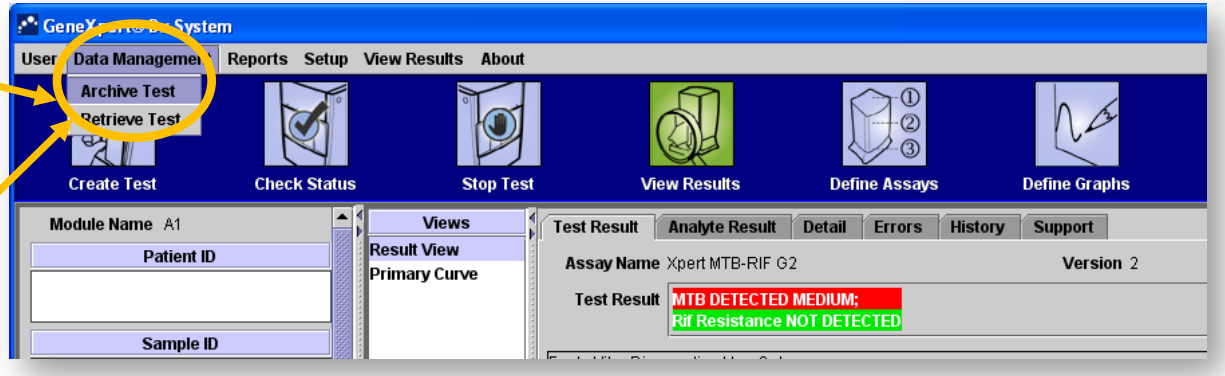
How to archive results

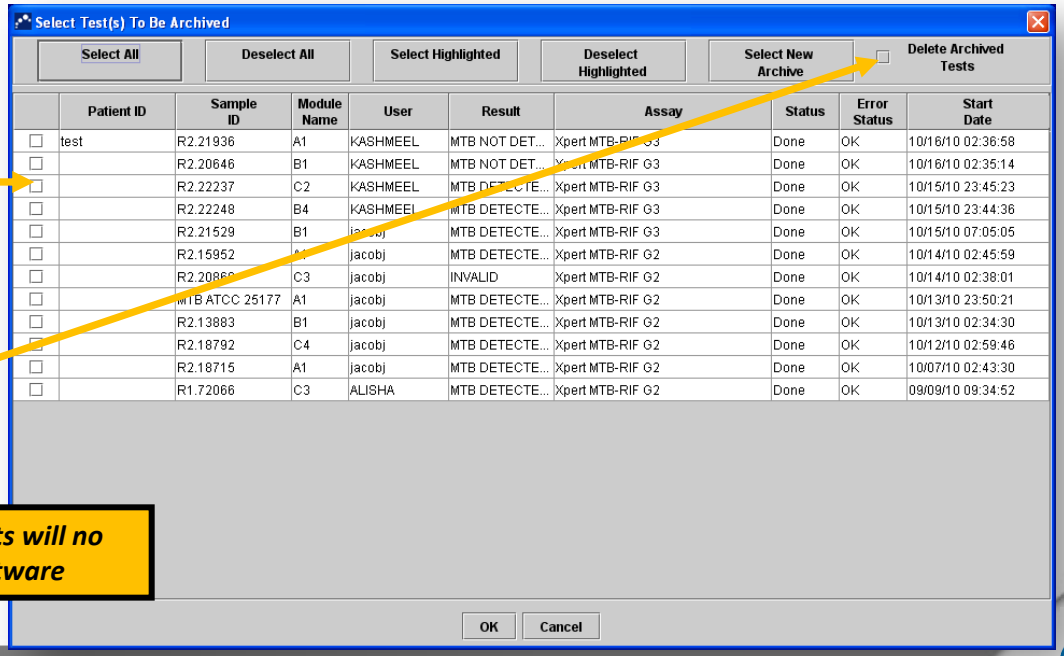
1 Click “Data Management”

2 Click “Archive test”



3 Choose the tests that need to be archived
Or “Select All”

4 You can choose to Delete Archived Tests



It means that the archived tests will no longer appear in the GxDx Software

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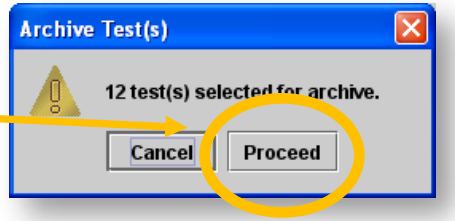
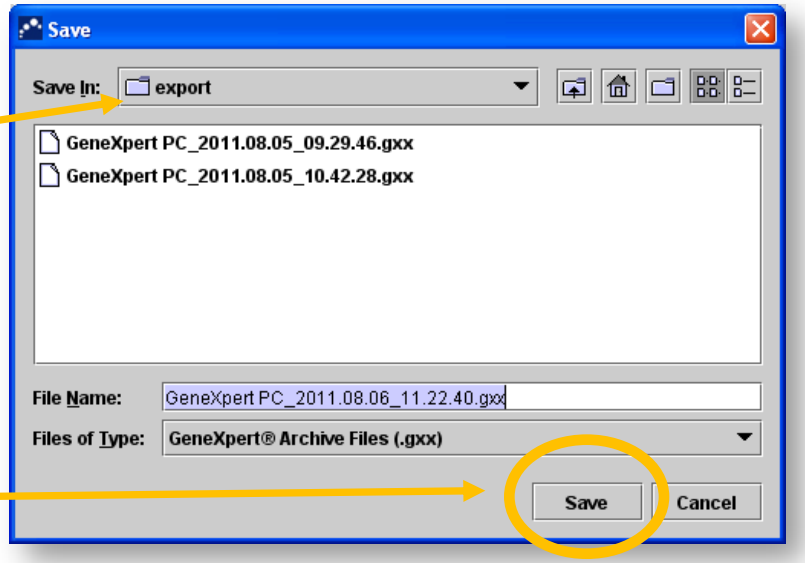
How to archive results

5 In the nest dialog box click “Proceed”



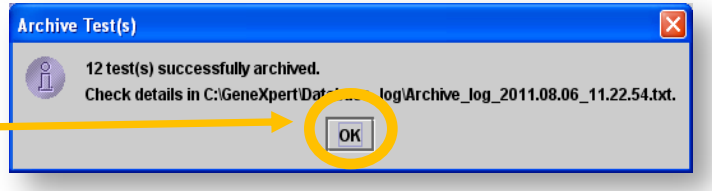
6 The files will be saved in the folder “Export”
In the file name you will see the date of archiving



It is highly advised to save (write) your archived data on a RW-CD

7 Click on “SAVE”

8 Click “OK”



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How to retrieve results

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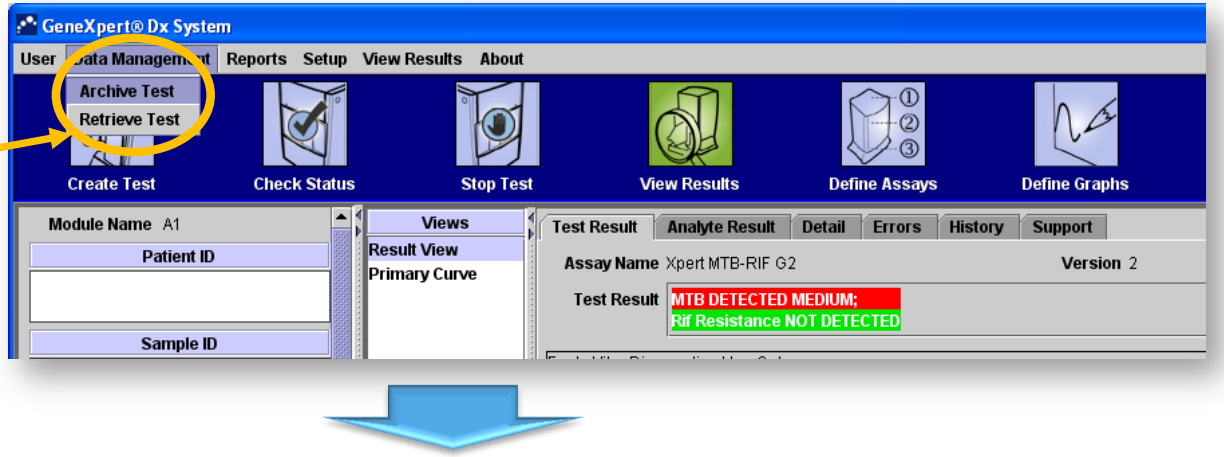
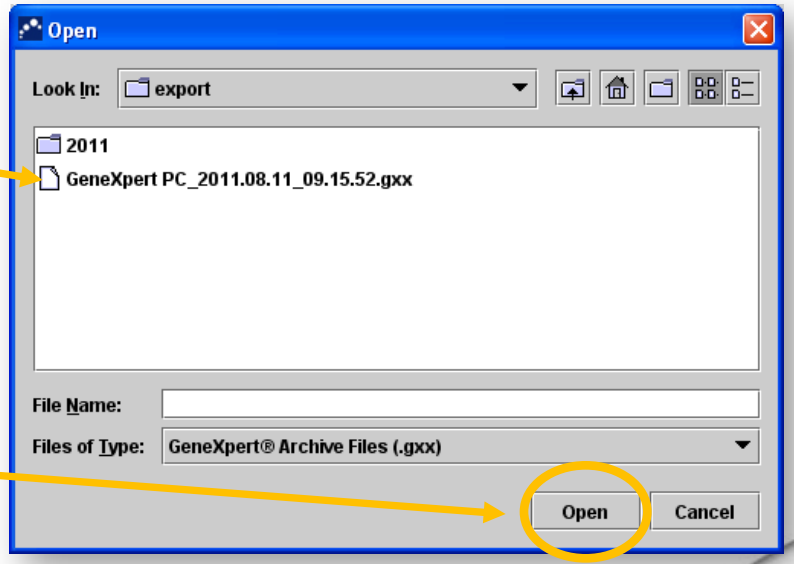
How to retrieve results

1 Click “Data Management” and Click “Retrieve Test”



2 Select the file you want to retrieve



3 Click on ”Open”

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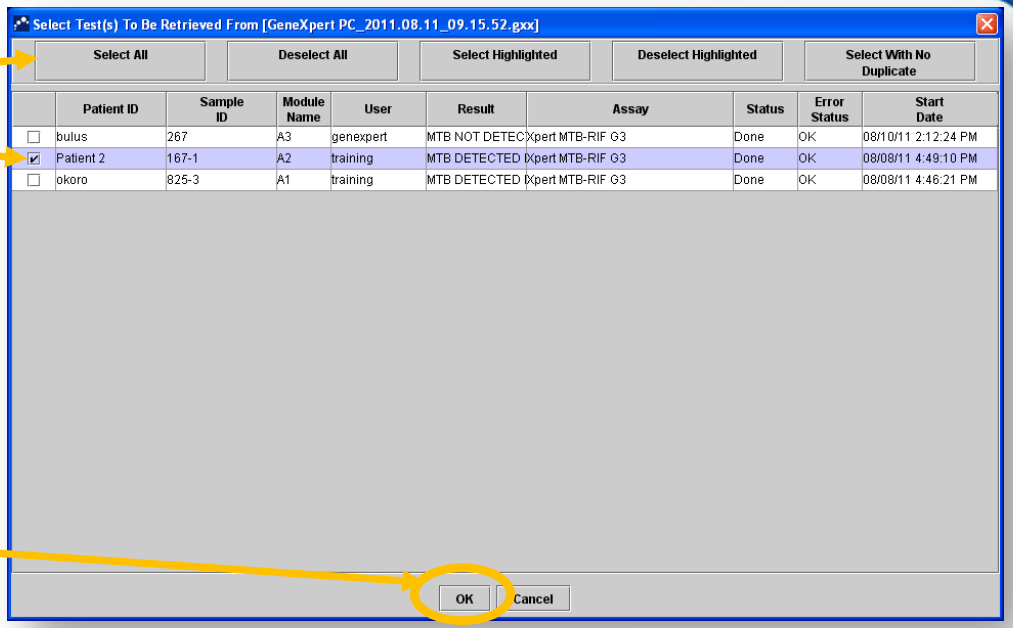
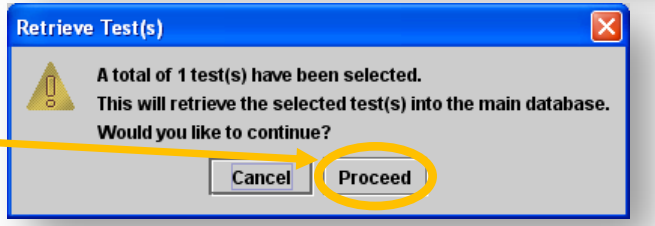
How to retrieve results

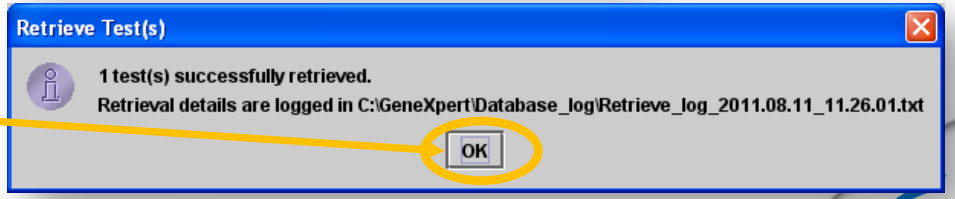
4 Select the test you may want to retrieve *(or Select All)*


Select Test(s) To Be Retrieved From [GeneXpert PC_2011.08.11_09.15.52.gxx]
Select All
Deselect All
Select Highlighted
Deselect Highlighted
Select With No Duplicate
Patient ID
Sample ID
Module Name
User
Result
Assay
Status
Error Status
Start Date
bulus 267 A3 genexpert MTB NOT DETEC Xpert MTB-RIF G3 Done OK 08/10/11 2:12:24 PM
Patient 2 167-1 A2 training MTB DETECTED Xpert MTB-RIF G3 Done OK 08/08/11 4:49:10 PM
okoro 825-3 A1 training MTB DETECTED Xpert MTB-RIF G3 Done OK 08/08/11 4:46:21 PM
OK
Cancel

5 Click OK


Retrieve Test(s)
A total of 1 test(s) have been selected.
This will retrieve the selected test(s) into the main database.
Would you like to continue?
Cancel
Proceed

6 Click “Proceed”



7 Нажмите OK

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How to backup the data

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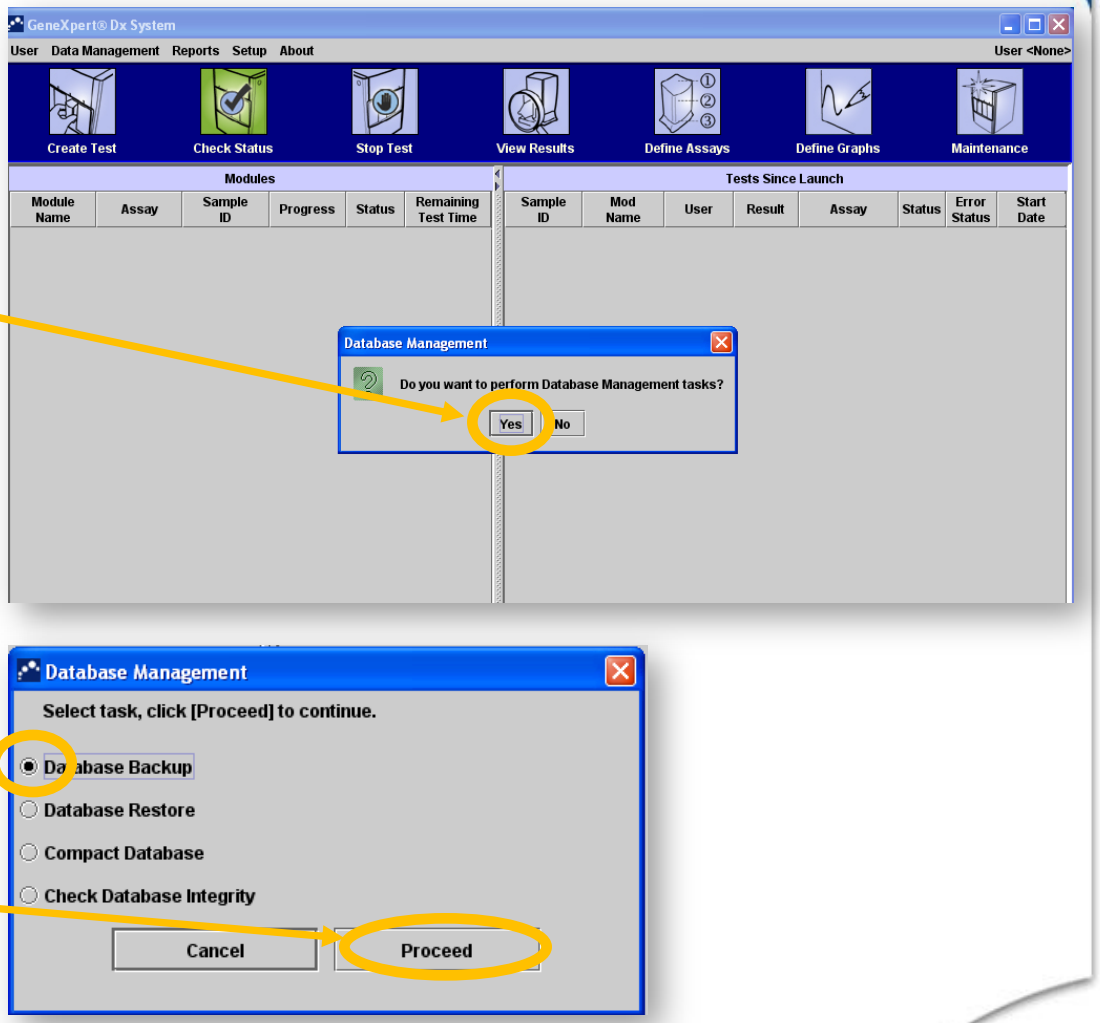
Data management tasks

At the end of the working day while closing the GeneXpert software, you will have the following screen:

1 Click on “YES”

2 Click on “Database Backup”

3 Click on “Proceed”



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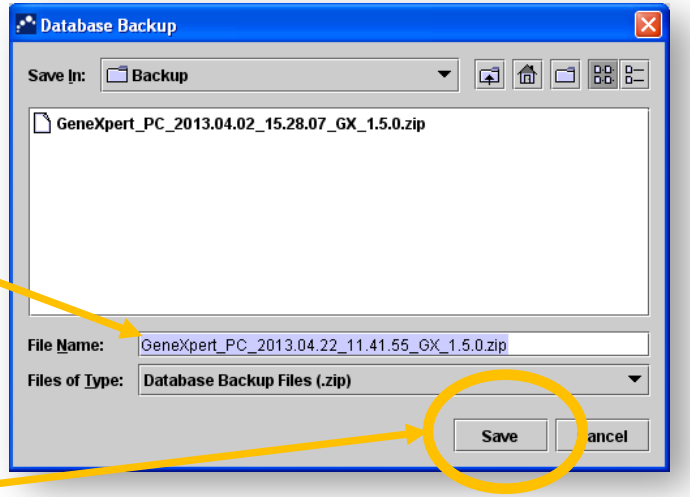
How to Create a Backup

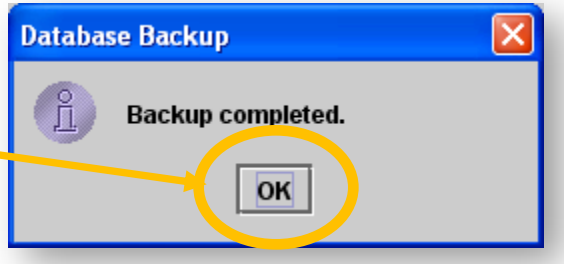
The software will create a zip file with all the results

The file is saved on the desktop, in the GeneXpert folder -> Backup section



4 Click on “SAVE”

5 Click “OK”



The zip file cannot be unzipped

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How to restore data from a backup

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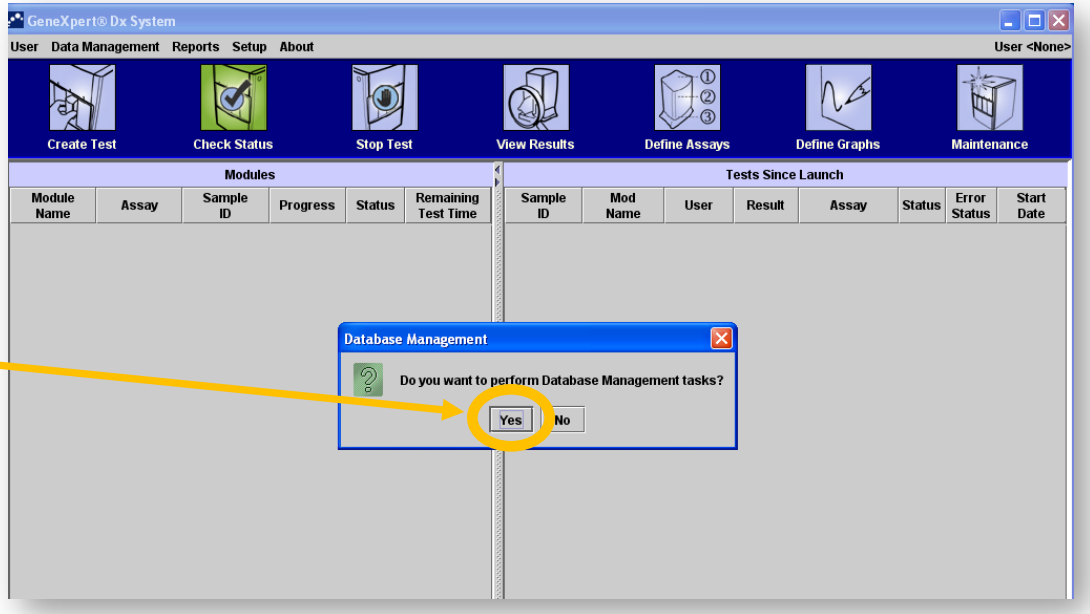
How to restore data

- In case of computer failure you might have to restore your data after reinstallation of all system.

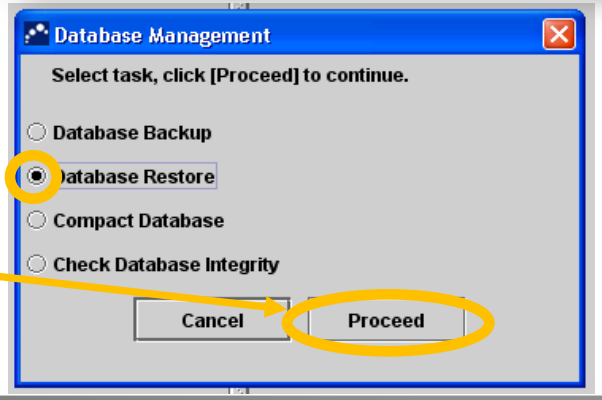
By closing the GeneXpert software, you will have the following screen:

1 Click on “YES”



2 Click on “Database Restore”

3 Click on “Proceed”



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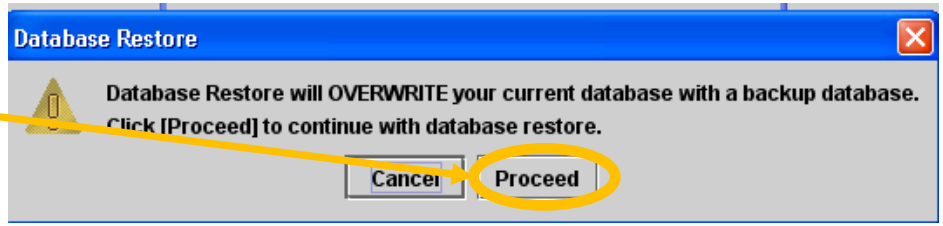
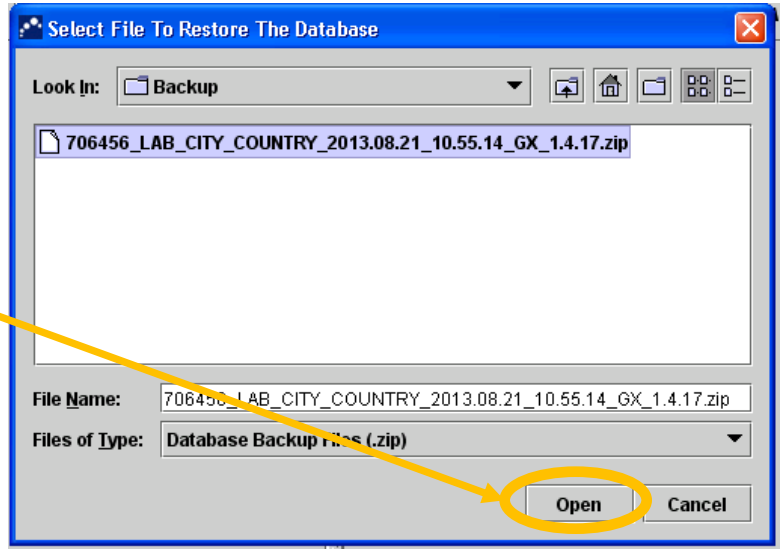
A warning message tells you that current database will be lost

Click « Procee » to continue


Database Restore
Database Restore will OVERWRITE your current database with a backup database.
Click [Proceed] to continue with database restore.
Cancel
Proceed

Select the database to be restored and Click « Open » to continue



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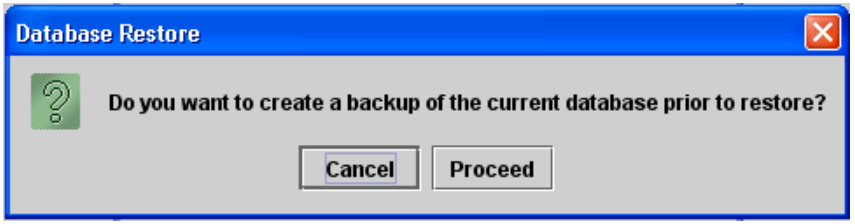
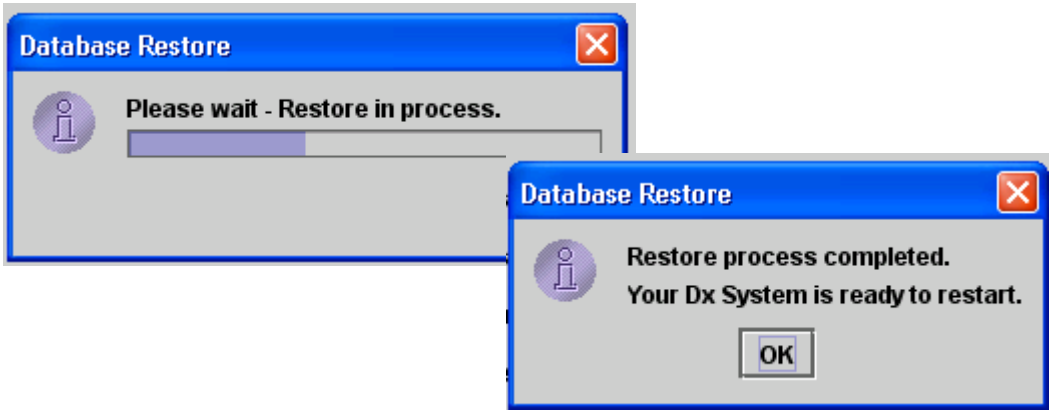
A dialog box asks you if you want to create a backup of the current database.
Click « Proceed » to create the backup
Click « Cancel » to continue Backup Restore





Import the Assay Definition File (ADF)

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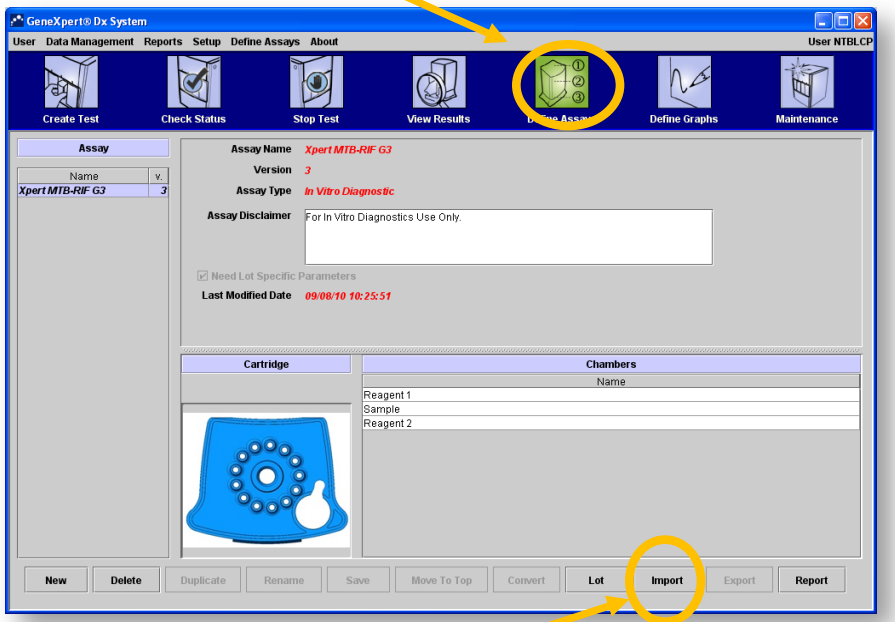
Import the Assay Definition File (ADF)

In case of test update, you have to import the ADF on the software. Before using this lot, load it from the CD provided with each kit

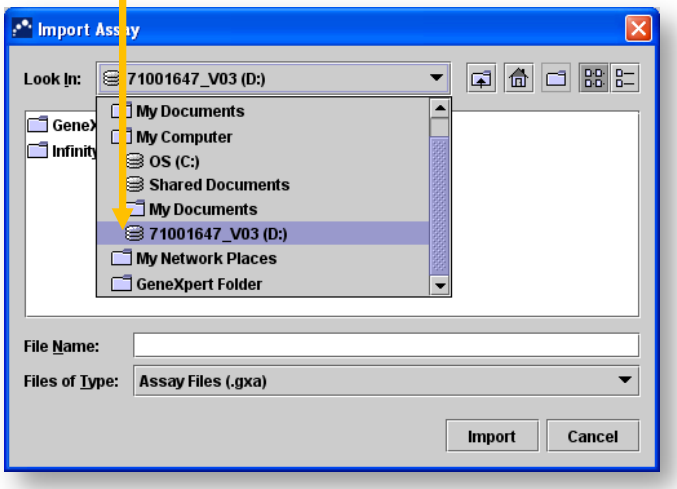
Insert the CD on the Computer CD drive

1 Click “DEFINE ASSAYS”



2 Click “IMPORT”

3 Find the CD



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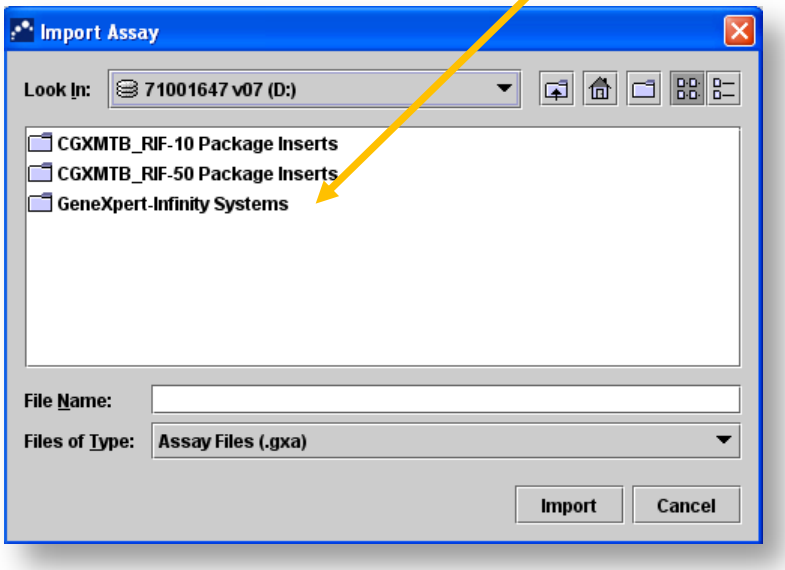
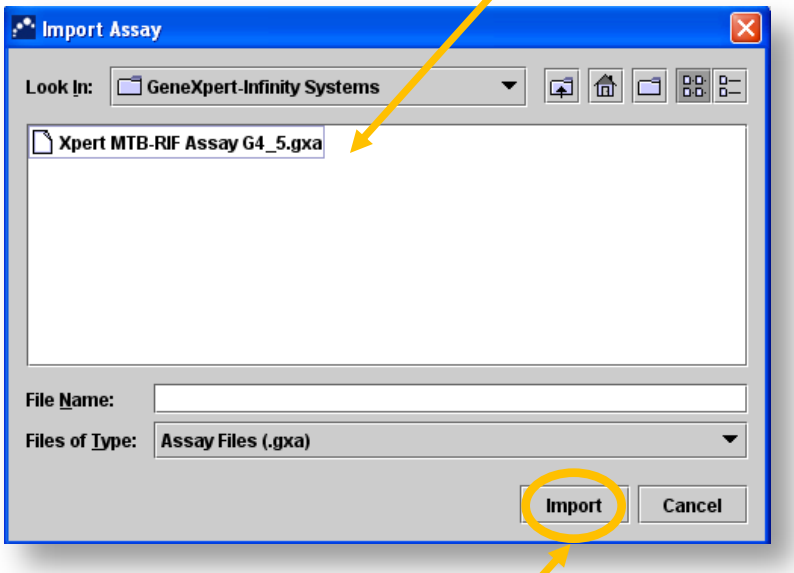
Import the Assay Definition File (ADF)

4 Open the folder“GeneXpert-Infinity Systems”



5 Choose the “Xpert MTB-RIF.gxa” file



6 Click on “IMPORT”

!!! ATTENTION!!!
The name of the file may vary from version to version.
In any case, load the file with the .gxa extension.

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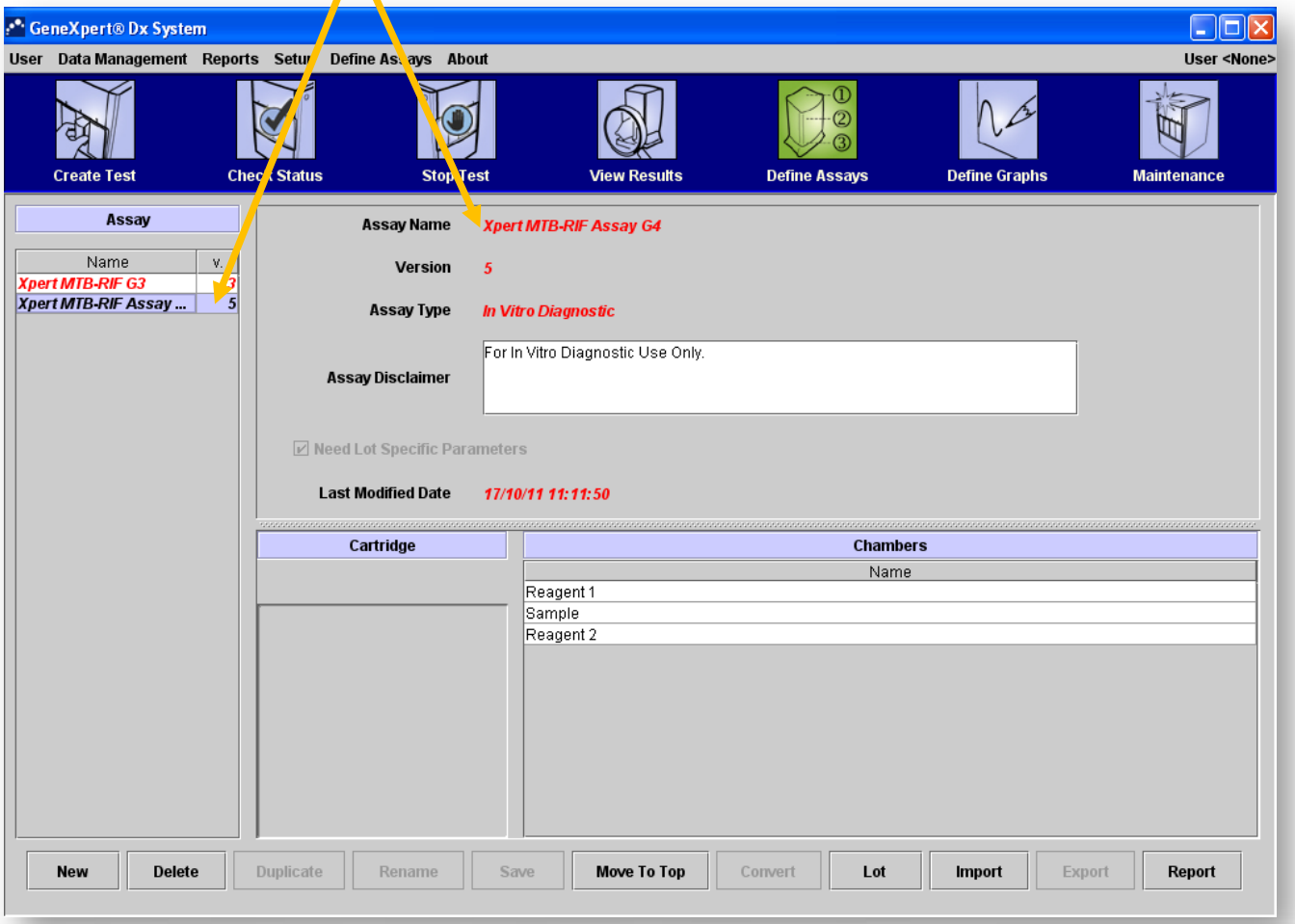
Import the Assay Definition File (ADF)

Now you can work with the new Assay Definition File
It will be showed here…



How to copy/paste data to excel

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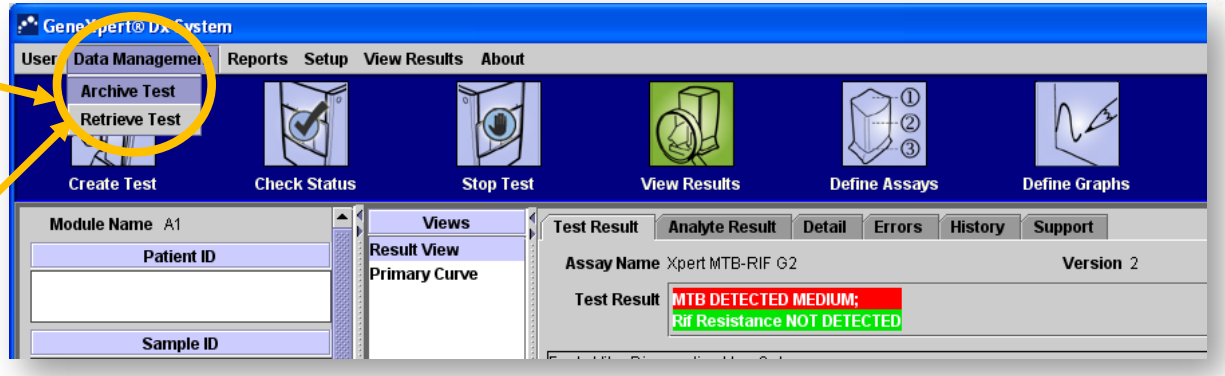
How to copy/paste data to excel

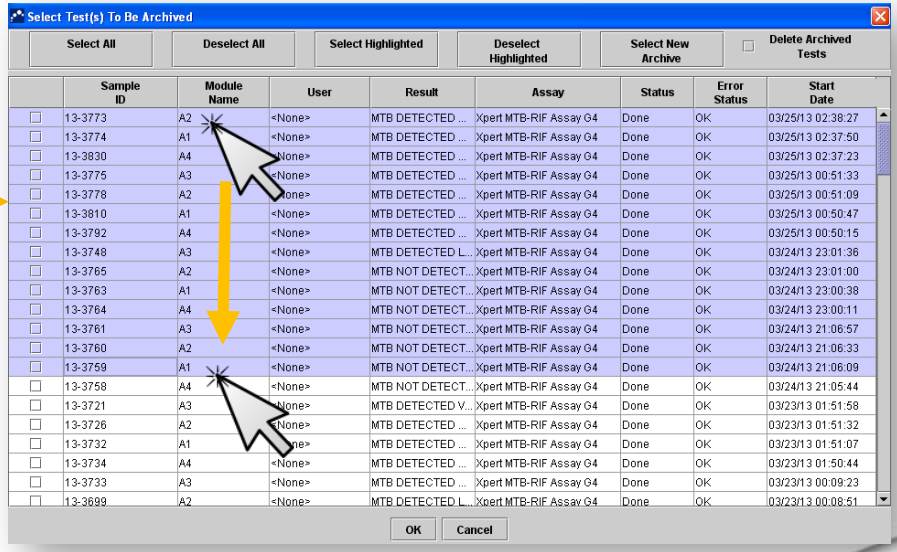
1 Click “Data Management”

2 Click “Archive test”



3 Put the mouse cursor on first test click and hold the left mouse button
Drag the mouse down until the last line

4 While the lines marked press Cltr + C at the same time on your keyboard

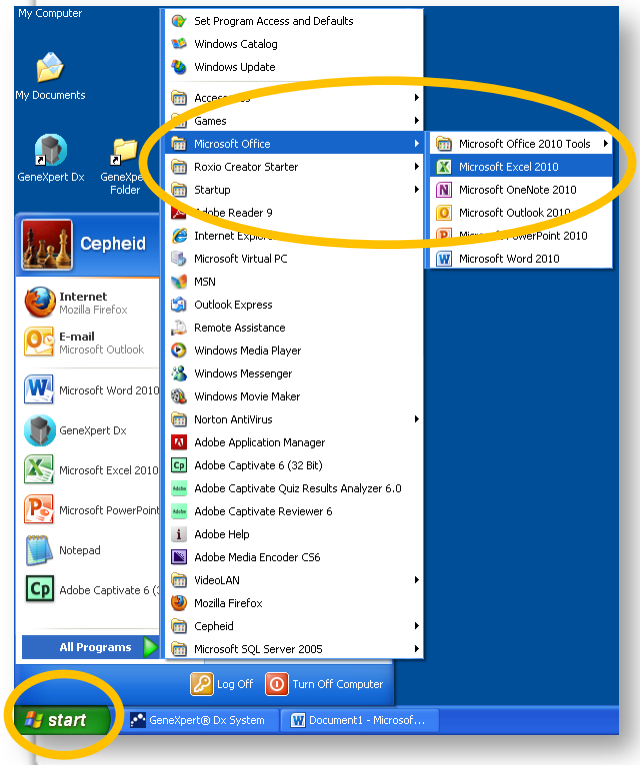


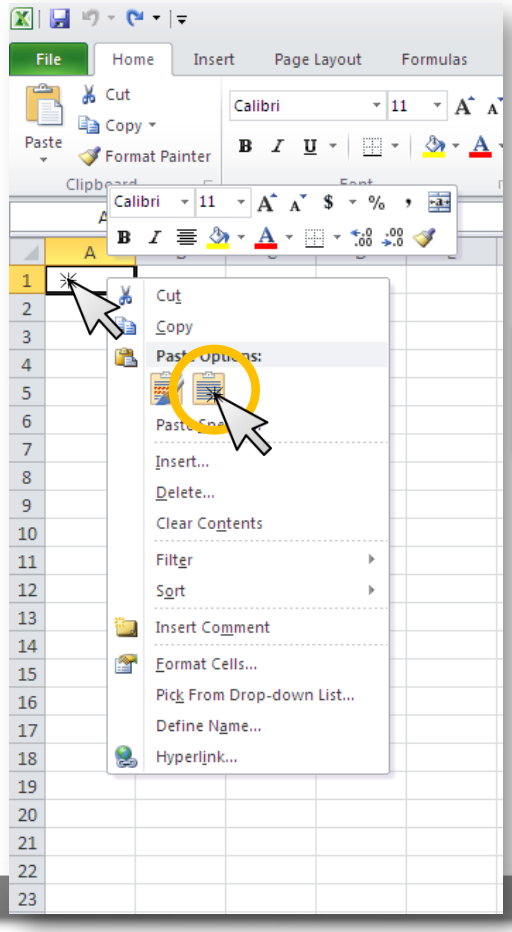
How to copy/paste data to excel

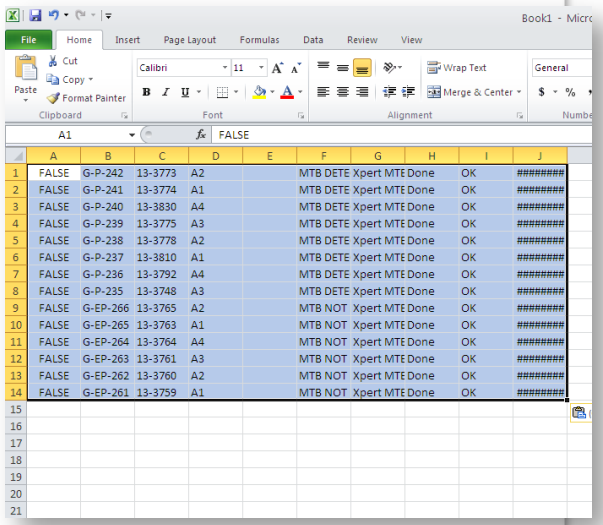
1 Open MS Excel by clicking Start -> All Programs -> Microsoft Office -> Microsoft Excel 2010

2 Click the right mouse button and in the menu and choose “Match destination Formatting” → click on it – *see below*

3 The chosen results will be pasted in excel sheet






Book1 - Micro
File
Home
Insert
Page Layout
Formulas
Data
Review
View
Cut
Copy
Format Painter
Paste
Calibri
11
Wrap Text
Merge & Center
General
Clipboard
Font
Alignment
A1
FALSE
FALSE G-P-242 13-3773 A2 MTB DETE Xpert MTE Done OK
FALSE G-P-241 13-3774 A1 MTB DETE Xpert MTE Done OK
FALSE G-P-240 13-3830 A4 MTB DETE Xpert MTE Done OK
FALSE G-P-239 13-3775 A3 MTB DETE Xpert MTE Done OK
FALSE G-P-238 13-3778 A2 MTB DETE Xpert MTE Done OK
FALSE G-P-237 13-3810 A1 MTB DETE Xpert MTE Done OK
FALSE G-P-236 13-3792 A4 MTB DETE Xpert MTE Done OK
FALSE G-P-235 13-3748 A3 MTB DETE Xpert MTE Done OK
FALSE G-EP-266 13-3765 A2 MTB NOT Xpert MTE Done OK
FALSE G-EP-265 13-3763 A1 MTB NOT Xpert MTE Done OK
FALSE G-EP-264 13-3764 A4 MTB NOT Xpert MTE Done OK
FALSE G-EP-263 13-3761 A3 MTB NOT Xpert MTE Done OK
FALSE G-EP-262 13-3760 A2 MTB NOT Xpert MTE Done OK
FALSE G-EP-261 13-3759 A1 MTB NOT Xpert MTE Done OK

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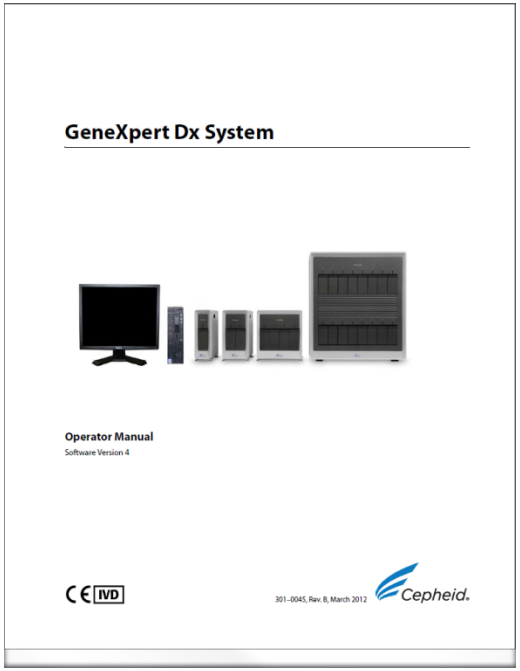
For information on GeneXpert DX Software

- **GeneXpert User Manual**



- **FTP server: ftp://hbdc:Crasa7Uc@ftp.caplaser.net**

Copy and paste the link in Windows Explorer (not Internet Explorer)